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.

Inhibitors of 6-hydroxymethyl-7,8-dihydropterin Pyrophosphokinase as Novel Antibiotics

Description of Invention: The invention offered for licensing describes and claims novel inhibitors of 6-hydroxymethyl-7,8-dihydropterin pyrophosphokinase (HPPK), a key enzyme in the folate biosynthetic pathway which is essential for microorganisms but absent in mammals. These novel inhibitors are based on linked purine pterin compounds. They can disrupt the folate biosynthesis of bacteria and thus can find utility as potential antimicrobials. Antibiotics based on these lead molecules can be specifically designed and synthesized to serve as broad-spectrum or narrow-spectrum antibiotics. None of the currently established antibiotics target HPPK.

Applications:

- Antimicrobial agents.
- Use in anti-bioterrorism.

Advantages:

- Potential as broad-spectrum or narrow-spectrum antibiotics.
- The antibiotics of present invention target a new biological pathway that has not been targeted by existing antibiotics, and thus circumvent issues related to drug resistance.

Inventors: Genbin Shi, Gary Shaw, Xinhua Ji (NCI).

Patent Status: U.S. Provisional Application No. 61/356,213 filed 18 Jun 2010 (HHS Reference No. E–170–2010/0–US–01).

Relevant Publications:

1. Blaszczyk J, Shi G, Li Y, Yan H, Ji X. Reaction trajectory of pyrophosphoryl transfer catalyzed by 6-hydroxymethyl-7,8-dihydropterin pyrophosphokinase. Structure 2004 Mar;12(3):467–475. [PubMed: 15016362].

2. Blaszczyk J, Shi G, Yan H, Ji X. Catalytic center assembly of HPPK as revealed by the crystal structure of a ternary complex at 1.25Å resolution. Structure 2000 Oct 15; 8(10):1049–1058. [PubMed: 11080626].

3. Wood HCS. 1975. Specific inhibition of dihydrofolate biosynthesis—a new approach to chemotherapy. Chemistry and Biology of Pteridines, W. Pfleiderer, ed. (Berlin-New York: Walter de Gruyter).

Licensing Status: Available for licensing.

Licensing Contacts:

- Uri Reichman, Ph.D., MBA; 301–435–4616; *UR7a@nih.gov.*
- John Stansberry, Ph.D.; 301–435–5236; *js852e@nih.gov.*

Collaborative Research Opportunity: The National Cancer Institute, Biomolecular Structure Section, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize the inhibitors of HPPK as novel antibiotics. Please contact John Hewes, PhD at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Compositions and Methods for the Treatment of Cancer

Description of Invention: Cancer is the second leading cause of human death next to coronary disease in the United States. Worldwide, millions of people die from cancer every year. In the United States alone, as reported by the American Cancer Society, cancer causes the death of well over a half-million people annually, with over 1.2 million new cases diagnosed per year. While deaths from heart disease have been declining significantly, those resulting from cancer generally are on the rise. Cancer is soon predicted to become the leading cause of death in the United States.

This application claims methods for inducing an immune response to a tumor. These methods include administering a therapeutically effective amount of apoptotic tumor cells conjugated to a K-type CpG oligodeoxynucleotide (ODN) to a subject. Methods for treating a tumor in a subject are also claimed in this application. These methods include administering a therapeutically effective amount of apoptotic tumor cells conjugated to a K-type CpG oligodeoxynucleotide (ODN) to a subject. More specifically, the tumor cells may be autologous, and the tumor may be a lymphoma, cervical cancer, prostate cancer, breast cancer, colon cancer, or a lung cancer.

Applications:

- Vaccines for the prevention of cancer and other indications
- Use of CpG oligonucleotides for prophylaxis and/or therapy

Advantages:

- Novel vaccine candidates
- Increased immunogenicity

Development Status: Preclinical studies have been conducted by the inventors.

Inventors: Dennis M. Klinman and Hidekazu Shirota (NCI).

Patent Status: U.S. Provisional Application No. 61/309,802 filed 02 Mar 2010 (HHS Reference No. E–266–2009/0–US–01).

Licensing Status: Available for licensing.

Licensing Contact: Peter A. Soukas; 301–435–4646; *soukasp@mail.nih.gov.*

Collaborative Research Opportunity: The Center for Cancer Research, Laboratory of Experimental Immunology, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize this technology. Please contact John Hewes, Ph.D. at 301–435–3121 or *hewesj@mail.nih.gov* for more information.

Dated: September 27, 2010.

Richard U. Rodriguez,

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

[FR Doc. 2010–24679 Filed 9–30–10; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0270]

Medical Device User Fee and Modernization Act; Notice to Public of Web site Location of Fiscal Year 2011 Proposed Guidance Development

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the Web site location where it will post a list of guidance documents the Center for Devices and Radiological Health (CDRH) is considering for development. In addition, FDA has established a docket where stakeholders may provide comments and/or draft language for those topics as well as suggestions for new or different guidances.

DATES: Submit either written or electronic comments at any time.

ADDRESSES: Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Nancy Pirt, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. WO66, rm. 4438, Silver Spring, MD 20993, 301–796–5739.

SUPPLEMENTARY INFORMATION:

I. Background

During negotiations over the reauthorization of the Medical Device User Fee and Modernization Act (MDUFMA), FDA agreed, in return for additional funding from industry, to meet a variety of quantitative and qualitative goals intended to help get safe and effective medical devices to market more quickly. These commitments include annually posting a list of guidance documents that CDRH is considering for development and providing stakeholders an opportunity to provide comments and/or draft language for those topics, or suggestions for new or different guidances. This notice announces the Web site location of the list of guidances on which CDRH is intending to work over the next Fiscal Year (FY). We note that the agency is not required to issue every guidance on the list, nor is it precluded from issuing guidance documents that are not on the list. The list includes topics that currently have no guidance associated with them, topics where updated guidance may be helpful, and topics for which CDRH has already issued level 1 drafts that may be finalized following review of public comments. We will consider stakeholder comments as we prioritize our guidance efforts.

FDA and CDRH priorities are subject to change at any time. Topics on this and past guidance priority lists may be removed or modified based on current priorities. We also note that CDRH's experience over the years has shown that there are many reasons CDRH staff does not complete the entire annual agenda of guidances it undertakes. Staff are frequently diverted from guidance development to other activities, including review of premarket submissions or postmarket problems. In addition, the Center is required each year to issue a number of guidances that it cannot anticipate at the time the annual list is generated. These may involve newly identified public health issues as well as special control guidance documents for de novo classifications of devices. It will be helpful, therefore, to receive comments that indicate the relative priority of different guidance topics to interested stakeholders.

Through feedback from stakeholders, including draft language for guidance documents, CDRH expects to be able to better prioritize and more efficiently draft guidances that will be useful to industry and other stakeholders. This will be the fourth annual list CDRH has posted. FDA intends to update the list each year.

FDA invites interested persons to submit comments on any or all of the guidance documents on the list. FDA has established a docket where comments about the FY 2011 list, draft language for guidance documents on those topics, and suggestions for new or different guidances may be submitted (see **ADDRESSES**). FDA believes this docket is an important tool for receiving information from interested parties and for sharing this information with the public. Similar information about planned guidance development is included in the annual agency-wide notice issued by FDA under its good guidance practices (21 CFR 10.115(f)(5)). This CDRH list, however, will be focused exclusively on device-related guidances and will be made available on FDA's Web site prior to the beginning of each FY from 2008 to 2012.

To access the list of the guidance documents CDRH is considering for development in FY 2011, visit the FDA Web site *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/MedicalDeviceUserFeeandModernizationActMDUFMA/ucm109196.htm*.

II. Request for Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 28, 2010.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2010–24669 Filed 9–30–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Disease Control and Prevention

Board of Scientific Counselors (BSC), National Center for Environmental Health/Agency for Toxic Substances and Disease Registry (NCEH/ATSDR)

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), CDC and NCEH/ATSDR announces the following committee meeting:

TIMES AND DATES:
8:30 a.m.–4:15 p.m., October 21, 2010.
8:30 a.m.–12 p.m., October 22, 2010.

PLACE: CDC, 4770 Buford Highway, Atlanta, Georgia 30341.

STATUS: Open to the public, limited only by the space available. The meeting room accommodates approximately 75 people.

PURPOSE: The Secretary, Department of Health and Human Services (HHS) and by delegation, the Director, CDC and Administrator, NCEH/ATSDR, are authorized under Section 301 (42 U.S.C. 241) and Section 311 (42 U.S.C. 243) of the Public Health Service Act, as amended, to: (1) Conduct, encourage, cooperate with, and assist other appropriate public authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and other impairments; (2) assist States and their political subdivisions in the prevention of infectious diseases and other preventable conditions and in the promotion of health and well being; and (3) train State and local personnel in health work. The BSC, NCEH/ATSDR provides advice and guidance to the Secretary, HHS; the Director, CDC and Administrator, ATSDR; and the Director, NCEH/ATSDR, regarding program goals, objectives, strategies, and priorities in fulfillment of the agency's