

first-served basis. Opportunities to address the panel during the meeting will occur during discussion of each topic, and speakers will be required to register ahead of time. If you would like to make a formal presentation during the open public sessions, you must register and provide an abstract of your presentation by 5 p.m. e.s.t. on January 15, 2010. To speak, submit your name, title, business affiliation (if applicable), address, telephone and fax numbers, and e-mail address to Adele Seifried (see **FOR FURTHER INFORMATION CONTACT**). FDA has included issues for comment in section I of the **SUPPLEMENTARY INFORMATION** section. You should also identify by letter each issue you wish to address in your presentation and the approximate time requested for your presentation.

FDA will do its best to accommodate those who wish to speak. Individuals and organizations with common interests are urged to consolidate or coordinate their comments and to request time for a joint presentation. FDA will determine the amount of time allotted to each presenter. Persons registered to make a formal presentation should check in before the workshop. In addition, we strongly encourage written comments to the docket. Written or electronic comments will be accepted until February 24, 2010.

If you need special accommodations because of disability, contact Adele Seifried (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the workshop.

### III. Comments

Regardless of attendance at the public workshop, interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. To ensure consideration, submit comments by (see **DATES**). Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

### IV. Transcripts

Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (see **ADDRESSES**). A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of

Information request. Written requests are to be sent to the Division of Freedom of Information (HFI-35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, rm. 6-30, Rockville, MD 20857.

Dated: October 27, 2009.

**David Horowitz,**

*Assistant Commissioner for Policy.*

[FR Doc. E9-26397 Filed 11-2-09; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### **Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): CDC Grants for Public Health Research Dissertation (Panel G), Funding Opportunity Announcement (FOA) PAR07-231, Initial Review**

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned SEP:

*Time and Date:* 12:30 p.m.–4:30 p.m., December 2, 2009 (Closed).

*Place:* Teleconference.

*Status:* The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.

*Matters To Be Discussed:* The meeting will include the initial review, discussion, and evaluation of applications received in response to “CDC Grants for Public Health Research Dissertation, FOA PAR07-231, Panel G.”

*Contact Person for More Information:* Maurine Goodman, MA, MPH, Scientific Review Administrator, CDC, 1600 Clifton Road, NE., Mailstop D72, Atlanta, GA 30333, Telephone (404) 639-4747.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: October 23, 2009.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E9-26283 Filed 11-2-09; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### **Prospective Grant of Exclusive License: Development of a Companion Diagnostic Kit To Detect Asparagine Synthetase Expression Levels as a Method To Screen for the Drug Efficacy in Treatments for Pancreatic Cancer, Ovarian Cancer, and Multiple Myeloma**

**AGENCY:** National Institutes of Health, Public Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This is notice, in accordance with 35 U.S.C. 209(c)(1) and 37 CFR 404.7(a)(1)(i), that the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in U.S. Patent Application No. 12/281,589 and PCT Application No. PCT/US07/05555 entitled “Materials and Methods Directed to Asparagine Synthetase and Asparaginase Therapies” (HHS Ref. No. E-132-2006/2), to the French-based ERYtech Pharma LLC which is located in Lyon, France (with an additional office in Philadelphia, Pennsylvania). The patent rights in this invention have been assigned to the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be for to the use of the Licensed Patent Rights limited to a FDA-approved companion diagnostic test predictive of L-asparaginase therapeutic effect in the treatment of pancreatic cancer, ovarian cancer, and multiple myeloma as claimed in the Licensed Patent Rights.

**DATES:** Only written comments and/or applications for a license which are received by the NIH Office of Technology Transfer on or before January 4, 2010 will be considered.

**ADDRESSES:** Requests for copies of the patent application, inquiries, comments, and other materials relating to the contemplated exclusive license should be directed to: Samuel E. Bish, Ph.D., Licensing and Patenting Manager, Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, MD 20852-3804; Telephone: (301) 435-5282; Facsimile: (301) 402-0220; E-mail: [bishse@mail.nih.gov](mailto:bishse@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The technology describes methods and therapies involving asparagine synthetase (ASNS) and L-asparaginase

(L-asp). Included are methods to decrease cell proliferation, most notably in order to treat various cancers, by administering to a subject a combination of an ASNS antagonist and a formulation of L-asp. The main ASNS antagonist utilized in these methods are small interfering RNAs (siRNAs) that reduce ASNS expression. Also included are methods of screening for the efficacy of L-asp in a subject by detecting the expression of the ASNS gene in a sample. The technology also describes a kit that probes to detect ASNS gene expression in a sample to identify the efficacy of L-asp treatment. ASNS serves as a key biomarker for acute lymphoblastic leukemia (ALL) and other malignancies because these cancer cells express little or no ASNS compared to normal cells. As a result, the cancerous cells must acquire asparagine from the bloodstream to survive and proliferate to form tumors. Over several decades, patients with ALL and other leukemias have been treated with L-asparaginase (L-asp) to break down asparagine in the body and starve leukemia cells of asparagine. L-asp treatment is usually more effective when ASNS expression in the patient is limited.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404.7. The prospective exclusive license may be granted unless within sixty (60) days from the date of this published notice, the NIH receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: October 26, 2009.

**Richard U. Rodriguez,**

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

[FR Doc. E9-26309 Filed 11-2-09; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF THE INTERIOR

### Minerals Management Service

[Docket No. MMS-2009-OMM-0015]

#### **MMS Information Collection Activity: 1010-0051, Oil and Gas Production Measurement, Extension of a Collection; Comment Request**

**AGENCY:** Minerals Management Service (MMS), Interior.

**ACTION:** Notice of extension of an information collection (1010-0051).

**SUMMARY:** To comply with the Paperwork Reduction Act of 1995 (PRA), MMS is inviting comments on a collection of information that we will submit to the Office of Management and Budget (OMB) for review and approval. The information collection request (ICR) concerns the paperwork requirements in the regulations under 30 CFR 250, Subpart L, Oil and Gas Production Measurement.

**DATES:** Submit written comments by January 4, 2010.

**FOR FURTHER INFORMATION CONTACT:**

Cheryl Blundon, Regulations and Standards Branch at (703) 787-1607. You may also contact Cheryl Blundon to obtain a copy, at no cost, of the regulation that requires the subject collection of information.

**ADDRESSES:** You may submit comments by either of the following methods listed below.

- *Electronically:* go to <http://www.regulations.gov>. In the entry titled "Enter Keyword or ID," enter docket ID MMS-2009-OMM-0015 then click search. Under the tab "View by Relevance" you can submit public comments and view supporting and related materials available for this collection of information. The MMS will post all comments.

- Mail or hand-carry comments to the Department of the Interior; Minerals Management Service; Attention: Cheryl Blundon; 381 Elden Street, MS-4024; Herndon, Virginia 20170-4817. Please reference Information Collection 1010-0051 in your subject line and mark your message for return receipt. Include your name and return address in your message text.

**SUPPLEMENTARY INFORMATION:**

*Title:* 30 CFR Part 250, Subpart L, Oil and Gas Production Measurement.

*OMB Control Number:* 1010-0051.

*Abstract:* The Outer Continental Shelf (OCS) Lands Act, as amended (43 U.S.C. 1331 *et seq.* and 43 U.S.C. 1801 *et seq.*), authorizes the Secretary of the Interior (Secretary) to prescribe rules and regulations to administer leasing of the

OCS. Such rules and regulations will apply to all operations conducted under a lease. Operations on the OCS must preserve, protect, and develop oil and natural gas resources in a manner that is consistent with the need to make such resources available to meet the Nation's energy needs as rapidly as possible; to balance orderly energy resource development with protection of human, marine, and coastal environments; to ensure the public a fair and equitable return on the resources of the OCS; and to preserve and maintain free enterprise competition. The Federal Oil and Gas Royalty Management Act of 1982 (30 U.S.C. 1701, *et seq.*) at section 1712(b)(2) prescribes that an operator will "develop and comply with such minimum site security measures as the Secretary deems appropriate, to protect oil or gas produced or stored on a lease site or on the Outer Continental Shelf from theft." Regulations at 30 CFR part 250, subpart L, implement these statutory requirements. We use the information to ensure that the volumes of hydrocarbons produced are measured accurately, and royalties are paid on the proper volumes. Specifically, MMS needs the information to:

- Determine if measurement equipment is properly installed, provides accurate measurement of production on which royalty is due, and is operating properly;
- Obtain rates of production data in allocating the volumes of production measured at royalty sales meters, which can be examined during field inspections;
- Ascertain if all removals of oil and condensate from the lease are reported;
- Determine the amount of oil that was shipped when measurements are taken by gauging the tanks rather than being measured by a meter;
- Ensure that the sales location is secure and production cannot be removed without the volumes being recorded; and
- Review proving reports to verify that data on run tickets are calculated and reported accurately.

The MMS will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2) and under regulations at 30 CFR 250.197, Data and information to be made available to the public or for limited inspection and 30 CFR part 252, OCS Oil and Gas Information Program. No items of a sensitive nature are collected. Responses are mandatory.

*Frequency:* Varies by section, but primarily monthly, or on occasion.