Dated: October 27, 2009

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9–26421 Filed 11–2–09; 8:45 am]

BILLING CODE 4140–01–P

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 D), 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 1, 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 D.''

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. E9–26389 Filed 11–2–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0519]

Public Workshop: International Conference on Harmonisation S2 Genetic Toxicology Issues; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''ICH S2 Genetic Toxicology Issues.'' The 1-day public workshop is intended to seek constructive input from experts in the field of genetic toxicology on proposed changes to the International Conference on Harmonisation (ICH) guidance ''S2(R1) Genotoxicity Testing and Data Interpretation for Pharmaceuticals Intended for Human Use'' that was published in March 2008.

DATES: The public workshop will be held on January 25, 2010, from 8:30 a.m. to 5 p.m. Register by January 15, 2010, to make a presentation at the workshop. See section II in the **SUPPLEMENTARY INFORMATION** section for information on how to attend the workshop. We are opening a docket to receive your written or electronic comments. Written or electronic comments must be submitted to the docket by February 24, 2010, to receive consideration.

ADDRESSES: The public workshop will be held at the Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, 5630 Fishers Lane, rm. 1066, Rockville, MD 20857. Submit written or electronic requests to make a presentation to Adele Seifried (see **FOR FURTHER INFORMATION CONTACT**). 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*. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Adele Seifried, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6482, Silver Spring, MD 20993–0002, 301–796–0535, FAX: 301–796–9855, e-mail: *Adele.Seifried@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Objectives

The objectives of this workshop are to provide a scientific forum where experts in the field of genetic toxicology can provide their views on proposed changes to ICH S2(R1). These proposed changes are described in the following paragraphs.

A. The Genetox Battery and Followup Testing: Options 1 and 2

The ICH steering committee agreed that revision of ICH S2 was appropriate because the 2 guidances that comprise it, ICH S2A and ICH S2B, were finalized nearly 15 years ago and much has been learned in the interim. ICH S2(R1) is a draft version that discusses the components of a basic genetic toxicology battery as well as in vivo followup testing that should be conducted when in vitro tests are positive. ICH S2(R1) offers two test options: Option 1 is similar to the current ICH and CDER test battery with some modifications. Option 2 removes the in vitro mammalian cell test from the test battery and instead includes two in vivo endpoints that can be assessed in a single assay. The workshop will examine these options in addressing what constitutes an adequate genetic toxicology battery, including which tests are reasonable followups to a positive in vitro cytogenetic assay or mouse lymphoma assay. The workshop will also examine the following: (1) Whether an in vivo comet assay is a reasonable followup test to a positive in vitro cytogenetic or mouse lymphoma assay, and if not, what alternatives exist, and (2) whether the two-option system being proposed would provide comparable or superior patient protection to the current single-option test battery.

B. Top Concentration for Mammalian In Vitro Genotoxicity Assays

The current ICH safety guidances specify that drug substances should be tested up to a concentration of 10 millimolars (mM) in vitro if no toxicity is seen at lower concentrations. The draft ICH S2(R1) proposes to lower this top concentration for required testing to 1 mM. This workshop will examine the scientific basis for this proposal and its potential effect on patient safety.

II. Attendance and Registration to Speak

There is no fee to attend the workshop, and attendees who do not wish to make a formal presentation to the scientific panel do not need to register. Seating will be on a first-come,

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*.

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