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]

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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,