DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Centers for Birth Defects Research and Prevention, Funding Opportunity Announcement (FOA) DD09–001

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 meeting.

Time and Date: 9 a.m.–2 p.m., October 7, 2008 (Closed).

Place: Centers for Disease Control and Prevention, Global Communications Center, 1600 Clifton Road, NE., Atlanta, GA 30333, 404–639–3138.

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 review, discussion, and evaluation of applications received in response to ''Centers for Birth Defects Research and Prevention, FOA DD09–001.''

Contact Person for More Information: Susan Stanton, D.D.S., Scientific Review Officer, Office of the Chief Science Officer, CDC, 1600 Clifton Road, NE., Mailstop D74, Atlanta, GA 30333, Telephone 404–639–4640.

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: August 22, 2008.

Elaine L. Baker,

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

[FR Doc. E8–19946 Filed 8–27–08; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0449]

Draft Guidance for Industry on Integrated Summary of Effectiveness; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Integrated Summary of Effectiveness.'' This draft guidance describes how an integrated summary of effectiveness (ISE) should be prepared by industry for new drug applications (NDAs) and biologics license applications (BLAs). This guidance, when final, will supersede section G, Integrated Summary of Effectiveness Data, of the 1988 guidance on ''Format and Content of the Clinical and Statistical Sections of an Application'' (Clin-Stat guidance). This guidance also incorporates the conceptual framework of section 2.7.3, Summary of Clinical Efficacy, from the International Conference on Harmonisation (ICH) guidance for industry ''M4E The CTD —Efficacy.'' This guidance is intended to improve the quality of product applications by describing what efficacy information should be submitted so that FDA can make a regulatory decision on an application.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by October 27, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained from the Center for Biologics Evaluation and Research by mail by calling 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the draft guidance 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*.

FOR FURTHER INFORMATION CONTACT:

Howard Chazin, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, rm. 6470, Silver Spring, MD 20993–0002, 301–796–0700; or

Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 576N, Rockville, MD 20852, 301–827–1053.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Integrated Summary of Effectiveness.'' This draft guidance describes how an ISE should be prepared by industry for NDAs and BLAs. The ISE has been required as part of an NDA submission (21 CFR 314.50(d)(5)(v)) since 1985, but the regulation does not describe the specific components of the ISE. The Clin-Stat guidance provides a description of what FDA recommends be included in an ISE. However, since the Clin-Stat guidance was published, several International Conference on Harmonisation guidances, including the ICH guidances for industry ''E3 Structure and Content of Clinical Study Reports,'' ''E10 Choice of Control Group and Related Issues in Clinical Trials,'' and ''M4E The CTD—Efficacy,'' have provided further recommendations for describing individual trials and providing results of efficacy analyses. This guidance, when final, will supersede section G of the Clin-Stat guidance to reflect FDA's current thinking regarding the format and content of the ISE to provide a truly integrated analysis, rather than a summary of efficacy results from individual clinical trials, and to satisfy FDA regulatory requirements. Although there are no corresponding regulations requiring an ISE for BLA submissions, applicants are encouraged to provide these analyses.

Regarding the common technical document, the ISE is often confused with the document included in Module 2, section 2.7.3, Summary of Clinical Efficacy. Although one of the goals of the ISE is to summarize the available effectiveness data, the ISE primarily is intended to be an integrated analysis of these data, going beyond a simple summary. The focus of the ISE is not on the detailed results of the individual studies, which are described in individual study reports, but a comprehensive, detailed, in-depth analysis that goes beyond individual study results to examine the basis for the entire approach taken.

This draft guidance is being issued consistent with FDA's good guidance