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Draft Guidance for Industry on Integrated Summary of Effectiveness; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Integrated Summary of Effectiveness.'' This draft guidance describes how an integrated summary of effectiveness (ISE) should be prepared by industry for new drug applications (NDAs) and biologics license applications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

practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the content and format of the ISE. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 have been approved under 0910–0001. The collections of information for submission of data in a BLA under 21 CFR 601.2 have been approved under 0910–0338.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

IV. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: August 19, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–19906 Filed 8–27–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2008–M–0084, FDA–2008–M–0100 (formerly 2008M–0013), FDA–2008–M–0182, FDA–2008–M–0109, FDA–2008–M–0207]

Medical Devices; Availability of Safety and Effectiveness Summaries for Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of premarket approval applications (PMAs) that have been approved. This list is intended to inform the public of the availability of safety and effectiveness summaries of approved PMAs through the Internet and the agency's Division of Dockets Management.

ADDRESSES: Submit written requests for copies of summaries of safety and effectiveness data to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Please cite the appropriate docket number as listed in Table 1 of this document when submitting a written request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries of safety and effectiveness.

FOR FURTHER INFORMATION CONTACT: Samie Allen, Center for Devices and Radiological Health (HFZ–402), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4013.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of January 30, 1998 (63 FR 4571), FDA published a final rule that revised 21 CFR 814.44(d) and 814.45(d) to discontinue individual publication of PMA approvals and denials in the **Federal Register**. Instead, the agency now posts this information on the Internet on FDA's home page at *http://www.fda.gov*. FDA believes that this procedure expedites public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than the **Federal Register**.

In accordance with section 515(d)(4) and (e)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(4) and (e)(2)), notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515(g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA begins on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant; in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

The regulations provide that FDA publish a quarterly list of available safety and effectiveness summaries of PMA approvals and denials that were announced during that quarter. The following is a list of approved PMAs for which summaries of safety and effectiveness were placed on the Internet from January 1, 2008, through March 31, 2008. There were no denial actions during this period. The list provides the manufacturer's name, the product's generic name or the trade name, and the approval date.

TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2008, THROUGH MARCH 31, 2008

PMA No. Docket No.	Applicant	TRADE NAME	Approval Date
P040021 (S004) FDA–2008–M–0084	St. Jude Medical, Inc.	SJM EPIC VALVE AND SJM SUPRA VALVE	November 15, 2007