within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, *Fax:* 202–395–6974, *Attn:* Desk Officer for the Administration for Children and Families.

Dated: April 16, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–9106 Filed 4–20–09; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0031] (formerly Docket No. 2007D–0233)

Guidance for Industry on Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.'' Since FDA began accepting new drug application (NDA) and biologics license application (BLA) submissions in the common technical document (CTD) format, there has been confusion regarding where within the CTD to include an integrated summary of effectiveness (ISE) and integrated summary of safety (ISS), both of which are required components of an NDA submission and recommended components of a BLA submission. This guidance informs applicants where to place the ISE and ISS in the CTD, addresses specific FDA requirements not discussed in the ICH guidance for industry ''M4E: The CTD—Efficacy,'' and is intended to improve application quality and consistency. This guidance finalizes the draft guidance of the same title published in the **Federal Register** of July 3, 2007 (72 FR 36471).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this 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, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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 Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.'' This guidance is intended for applicants submitting an NDA or BLA in the CTD or electronic common technical document (eCTD) format. Since FDA adopted the CTD, a standard way to organize a marketing or licensing application, there has been confusion regarding where to place an ISE and ISS within the CTD. The ISE and ISS are unique requirements of the United States and are not addressed fully by ICH M4E.

FDA considers the ISE and ISS critical components of the clinical efficacy and safety portions of a marketing or licensing application. Therefore, the ISE and ISS are required in NDA applications submitted to FDA in accordance with the regulations in 21 CFR 314.50(d)(5)(v) and (d)(5)(vi)(a). Although there are no corresponding regulations requiring an ISE or ISS for BLAs, applicants are encouraged to provide these analyses.

A common problem with the way many of the CTD-formatted applications are submitted is that applicants incorrectly assume that the clinical summaries in Module 2 satisfy the regulatory requirements for the ISE and ISS. This assumption can result in a determination by FDA that an application is incomplete. Despite their names, the ISE and ISS are detailed integrated analyses of all relevant data from the clinical study reports, not summaries. This guidance focuses on where to place ISE and ISS documents within the structure of the CTD or eCTD.

This guidance updates the part of sections II.G. and H. of the guidance on the ''Format and Content of the Clinical and Statistical Sections of an Application'' that relates to placement of the ISE and ISS. This guidance finalizes the draft guidance of the same title that published in the **Federal Register** of July 3, 2007 (72 FR 36471). No public comments were received regarding the draft guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on the location for an ISE and ISS within the CTD. 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. 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.

III. Electronic Access

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

Dated: April 10, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–9051 Filed 4–20–09; 8:45 am]

BILLING CODE 4160–01–S