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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier J. Hawkins

[Docket No. 2007D-0233]

Draft Guidance for Industry on Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document.”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 much 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 on where to place the ISE and ISS in the CTD. This guidance addresses specific FDA requirements not discussed in the ICH guidance for industry M4E: The CTD—Efficacy. This guidance is intended to improve application quality and consistency.

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on any guidance at any time (see 21 CFR 10.115 (g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit

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written or electronic comments on the draft guidance by [*insert date 60 days after date of publication in the **Federal Register***].

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. 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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft 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 Leonard Wilson, Center for Biologics Evaluation and Research (HFM-25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301-827-0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft 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 much 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.

The pertinent Federal regulations that require an ISE and an ISS for NDAs are §§ 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a), respectively (21 CFR 314.50(d)(5)(v) and 314.50(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 the applicants incorrectly assume that the clinical summaries in Module 2 satisfy the regulatory requirement for the ISE and ISS. This assumption can result in a determination by FDA that an application is incomplete. The ISE and ISS are detailed integrated analyses of all relevant data from the clinical study reports, not summaries, despite their names. 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 applications submitted to the FDA in accordance with the regulations (§§ 314.50(d)(5)(v) and 314.50(d)(5)(vi)(a)). This guidance focuses on where to place ISE and ISS documents within the structure of the CTD or eCTD.

When finalized, this guidance will update, in the guidance on the format and content of the clinical and statistical sections of an application, the part of sections II.G and H that relates to placement of the ISE and ISS.

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 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.fda.gov/ohrms/dockets/default.htm>.

Dated: 6/22/07
June 22, 2007

Jeffrey Shuren,
Assistant Commissioner for Policy.

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