''supporting data satisfying the requirements of § 860.7'' referred to is ''valid scientific evidence.''

For the purpose of reclassification, the valid scientific evidence upon which the agency relies must be publicly available. Publicly available information excludes trade secret and/or confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).)

II. Reclassification under SMDA

SMDA further amended the act to change the definition of a class II device. Under SMDA, class II devices are those devices which cannot be classified into class I because general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance, including performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary (section 513(a)(1)(B) of the act). Thus, the definition of a class II device was changed from ''performance standards'' to ''special controls.'' In order for a device to be reclassified from class II into class I, the agency must determine that special controls are not necessary to provide reasonable assurance of its safety and effectiveness.

III. Background

In the **Federal Register** of September 4, 1979 (44 FR 51732), FDA issued a final rule classifying the cutaneous electrode into class II (21 CFR 882.1320). The preamble to the proposal to classify the device included the recommendation of the Neurological Device Classification Panel (the Panel). The Panel's recommendation, among other things, identified the following risks to health associated with the use of the device: (1) Burns, since poor design or incorrect application of the electrodes could result in skin burns when the device is used to apply stimulation and (2) toxic reactions, since materials or substances in the electrodes that are in contact with the skin could produce adverse reactions.

The panel recommended that cutaneous electrodes be classified as class II because the electrical properties of the device must be controlled to assure that, when physiological signals are recorded, they are adequately reproduced. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily. Additionally, the panel recommended Class II to assure that only materials with known and acceptable properties are used in electrodes.

On May 31, 2005, FDA received a petition requesting that FDA reclassify electroencephalogram electrodes from class II to class I (Ref. 1). Under § 860.120(b) (21 CFR 860.120(b)), the reclassification of any device within a generic type of devices causes the reclassification of all substantially equivalent devices within that generic type of device.

IV. Device Description

The electroencephalogram electrode device is classified within the generic type of device cutaneous electrode (21 CFR 882.1320). FDA identifies cutaneous electrode as an electrode that is applied directly to a patient's skin either to record physiological signals (e.g., the electroencephalogram) or to apply electrical stimulation.

V. FDA's Decision

After reviewing the reclassification petition, FDA has found that the petition contains insufficient valid scientific evidence to allow FDA to determine that general controls would provide reasonable assurance of the device's safety and effectiveness for its intended use. FDA, therefore, is denying the petition.

VI. Reasons for the Denial

FDA has determined that Scientific Laboratory Products LTD., has not presented sufficient new scientific information to support the requested change in classification of this device. According to § 860.120(b), the reclassification of any device within a generic type of device causes the reclassification of all substantially equivalent devices within that generic type. Accordingly, a petition for the reclassification of a specific device will be considered a petition for reclassification of all substantially equivalent devices within the same generic type. The petitioner has not provided any evidence to reclassify their own device or the generic cutaneous electrode device category.

FDA believes that the petition lacks sufficient valid scientific evidence to allow the agency to determine that general controls would provide reasonable assurance of the safety and effectiveness of the cutaneous electrode for its intended use. Therefore, the cutaneous electrode shall be retained in class II.

VII. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from Scientific Laboratory Products LTD., for the reclassification of the electroencephalogram electrode device, dated May 16, 2005.

Dated: June 25, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–12882 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[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 written or electronic comments on the draft guidance by September 4, 2007.

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: June 22, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–12792 Filed 7–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D–0197]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies.'' This guidance document describes a means by which filtering facepiece respirators for use by the general public in public health medical emergencies may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify the filtering facepiece respirator for use by the general public in public health medical emergencies into class II (special controls). This guidance document is immediately in effect as a special control for the filtering facepiece respirator for use by the general public in public health medical emergencies, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance document are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to