

final version of the guidance, submit written or electronic comments on the draft guidance by September 4, 2007.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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FDA is announcing the availability of a draft guidance for industry entitled "Integrated Summaries of Effectiveness and Safety: Location Within the Common Technical Document."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.*

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**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

assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this 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.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** Sheila Murphey, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3700.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying the filtering facepiece respirator for use by the general public in public health medical emergencies into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as a special control for the filtering facepiece respirator for use by the general public in public health medical emergencies. An additional special control is established in 21 CFR 880.6260. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the timeframes established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response

to this notice to determine whether to amend the guidance document.

**II. Significance of Guidance**

This guidance is being issued consistent with FDA's GGP's regulation (§ 10.115). The guidance represents the agency's current thinking on special controls for the filtering facepiece respirator for use by the general public in public health medical emergencies. 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 statute and regulations.

**III. Electronic Access**

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive "Class II Special Controls Guidance Document: Filtering Facepiece Respirator for Use by the General Public in Public Health Medical Emergencies," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1626 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

**IV. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations and in NIOSH regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR

part 807, subpart E, have been approved under OMB Control No. 0910-0120; the collections of information in 21 CFR part 801 have been approved under OMB Control No. 0910-0485; and the collections of information in 42 CFR part 84 (relating to NIOSH certification) have been approved under OMB Control No. 0920-0109. In addition, FDA concludes that the labeling statement in section 10.A of the guidance does not constitute a "collection of information" under the Paperwork Reduction Act of 1995. Rather, this labeling statement is "public disclosure of information originally supplied by the Federal government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

**V. 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.

Dated: June 22, 2007.

**Linda S. Kahan,**

*Deputy Director, Center for Devices and Radiological Health.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2007D-0234]

**Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Class II Special Controls Guidance Document: Tissue Adhesive for the Topical Approximation of Skin." This draft guidance document describes a means by which the tissue adhesive for the topical approximation of skin may comply with the requirement of