Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*. 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, 240–276–3747.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance is for biological indicator devices intended for use in health care facilities to monitor the effectiveness of sterilizers. Biological sterilization process indicators are class II devices identified in 21 CFR 880.2800(a). In the **Federal Register** of May 21, 2001 (66 FR 27985), FDA invited interested persons to comment on the draft guidance entitled ''Premarket Notifications [510(k)] for Biological Indicators Intended to Monitor Sterilizers Used in Health Care Facilities; Draft Guidance for Industry and FDA Reviewers.''

FDA received five comments on the draft guidance. Many of the comments are addressed by the voluntary consensus standards that have been recognized by FDA since the draft was issued and that are now cited in the guidance. We addressed comments that suggested the statistics in the validation protocol were too restrictive by clarifying that these statistics are examples, not thresholds. We also revised the guidance for clarity and brevity in response to the comments received.

II. Significance of 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 ''biological indicator premarket notification submissions.'' 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 ''Biological Indicator (BI) Premarket Notification (510(k)) Submissions'' you may either send an e-mail request to *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 1320 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. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collections of information in 21 CFR part 807, subpart E have been approved under OMB Control Number 0910–0120. The labeling provisions addressed in the guidance have been approved under OMB Control Number 0910–0485.

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: September 26, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–19573 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0309]

Draft Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Electrocardiograph Electrodes; 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: Electrocardiograph Electrodes.'' The draft guidance describes a means by which the electrocardiograph electrode device may comply with the requirement of special controls for class II devices. Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate this draft guidance as the special control for this device and would exempt the device from premarket notification requirements, subject to specific limitations, if the device addresses the issues identified in the guidance by following its recommendations. The draft guidance document is not final, nor is it being implemented at this time.

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 January 2, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes'' 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 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 either*http://www.fda.gov/dockets/ecomments* or*http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sharon Lappalainen, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–4095, or by e-mail at *Sharon.Lappalainen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 5, 1980 (45 FR 7926), FDA issued a final rule classifying the electrocardiograph electrode into class II, under the Federal Food, Drug, and Cosmetic Act (the act). An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram. FDA has now developed a draft guidance document for the device and, under the act's provisions, is proposing to designate the draft guidance as the special control that, when combined with the general controls, the agency believes will provide a reasonable assurance of the safety and effectiveness of this device type.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate this draft guidance document as the special control for this device and would exempt the device from premarket notification requirements, subject to limitations in 21 CFR 870.9, if the device addresses the issues identified in the special controls guidance by following the draft guidance's recommendations.

The draft special controls guidance document identifies the classification, product code, and classification identification for the electrocardiograph electrode device. In addition, the draft guidance document identifies the risks to health and serves as a special control that, when followed and combined with the general controls, will generally address the risks associated with this generic device type and permit introduction of the device to the market.

II. Significance of Guidance

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 device. 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, regulations, or both.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. To receive ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes'' you may either send an e-mail request to *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 (1597) 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 draft guidance refers to previously approved collections of information found in FDA 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 number 0910–0120; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

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: September 26, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–19578 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0348]

Establishing a Docket for the Development of Safety and Effectiveness Assessments of Vaccines Used for Pandemic Influenza; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opening of a docket to receive information and comments from manufacturers of vaccines and other interested persons concerning the development of safety and effectiveness assessments of vaccines used for pandemic influenza. FDA is interested in obtaining comments and information to aid in the development of programs for adverse events surveillance following administration of pandemic influenza vaccines, and in the development of protocols to study effectiveness of influenza vaccines in pre-pandemic and pandemic situations.

DATES: Submit written or electronic comments on the safety and effectiveness assessments of vaccines for pandemic influenza use, and comments on information submitted to the docket by other interested persons by December 3, 2007.

ADDRESSES: Submit written comments and information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852–1448. Submit electronic comments or information to either *http://www.fda.gov/dockets/ecomments* or *http://www.regulations.gov*.