DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. 2007N–0308]

Medical Devices; Cardiovascular Devices; Electrocardiograph Electrode; Designation of Special Controls

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the classification regulation for the electrocardiograph electrode device to establish special controls and to exempt the device from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the act). The agency is taking this action on its own initiative. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance document that would serve as the special control for the device if the rule is finalized. The agency believes that special controls, when followed and combined with the general controls, will provide reasonable assurance of the safety and effectiveness of these devices, if this proposal becomes final.

DATES: Submit written or electronic comments by January 2, 2008. See section VI of this document for the proposed effective date of a final rule based on this proposed rule.

ADDRESSES: You may submit comments, identified by Docket No. 2007N–0308, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following ways:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments*. Follow the instructions for submitting comments on the agency Web site.

Written Submissions

Submit written submissions in the following ways:

- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD–ROM submissions]: Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

To ensure more timely processing of comments, FDA is no longer accepting comments submitted to the agency by e-mail. FDA encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal or the agency Web site, as described previously in the **ADDRESSES** portion of this paragraph under *Electronic Submissions*.

Instructions: All submissions received must include the agency name and Docket No(s). and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments received may be posted without change to *http://www.fda.gov/ohrms/dockets/default.htm*, including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/ohrms/dockets/default.htm* and insert the docket number(s), found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

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, *Sharon.Lappalainen@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background (Regulatory Authorities)

The act (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Public Law 94–295), the Safe Medical Devices Act (SMDA) (Public Law 101–629), and the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Public Law 105–115), established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as preamendments devices. Under the 1976 amendments, class II devices are identified as those devices in which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness of the device, but for which there is sufficient information to establish a performance standard to provide such assurance.

SMDA broadened the definition of class II devices to include those devices for which general controls would not provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. The special controls include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary to provide such assurance. (See section 513(a)(1)(B) of the act.)

FDAMA added, among other sections, section 510(m) to the act (21 U.S.C. 360(m)). Under section 510(m) of the act, FDA may exempt a class II device from premarket notification requirements (510(k)), if the agency determines that premarket notification is not necessary to assure the safety and effectiveness of the device. This section requires FDA to publish in the **Federal Register** a notice of intent to exempt a device and provide a comment period.

II. Regulatory History of the Device

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 1976 amendments. 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.

III. Proposed Rule

FDA is proposing to amend the classification regulation of the electrocardiograph electrode device in order to designate a special control for the device. The device was classified before the provisions of SMDA broadened the definition of class II devices to establish special controls beyond performance standards. Therefore, designating a special controls guidance document as a means to provide reasonable assurance of the safety and effectiveness of the device was not a regulatory option at the time of the original classification.

Under the authority provided by SMDA, FDA is now able to propose the designation of a draft guidance

document as a special control the agency believes will, together with the general controls, reasonably assure the safety and effectiveness of the device. FDA is identifying the draft guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes'' as the proposed special control for the electrocardiograph electrode device. This draft guidance document describes means by which the device may comply with the requirement of special controls for class II devices. The draft guidance document identifies the issues associated with the device and recommends measures to address the issues.

Under section 510(m)(2) of the act, FDA is proposing to exempt the device from premarket notification, subject to the limitations of § 870.9 (21 CFR 870.9), if the device addresses the issues identified in the special controls guidance by following the specific measures recommended in the special controls guidance.

IV. Risks to Health

FDA has identified the following risks to health associated with these devices: Adverse tissue reaction to the skin-contacting electrode materials and misdiagnosis.

A. Adverse Tissue Reaction to the Skin-Contacting Electrode Materials

Some of the skin contacting materials of the electrode may not be biocompatible. Inadequate biocompatibility may result in adverse tissue reactions such as redness, burning sensation, and rash.

B. Misdiagnosis

Inadequate electrical performance may result in poor signal measurement. Inadequate labeling regarding proper electrical performance may result in improper use and cause poor signal measurement. Poor signal measurement may result in misdiagnosis of cardiac conditions.

V. Special Controls

FDA believes that, in addition to general controls, the class II special controls draft guidance document entitled ''Class II Special Controls Guidance: Electrocardiograph Electrodes'' is an adequate special control to help address the risks to health described in section IV of this document. The class II special controls draft guidance document provides information on how to mitigate the risks to health of adverse tissue reaction to skin contacting electrode materials and misdiagnosis, by recommending testing and labeling.

Several consensus standards describe electrical performance testing and properties to address the risk of misdiagnosis. Another consensus standard recommends biocompatibility testing, which can address the risk of adverse tissue reaction by ensuring that the device materials are sufficiently biocompatible for use on the skin.

The labeling recommendations in the draft guidance document address the risk of improper use by recommending that manufacturers, consistent with the general labeling provisions of 21 CFR part 801, include the duration of application to the skin, instructions for skin preparation, and instructions for electrode preparation, cleaning, and maintenance in their labeling.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the draft guidance document that would serve as the special control for these devices.

VI. Proposed Effective Date

FDA proposes that any final rule that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**. If finalized, following the effective date of a final rule, any firm intending to market the device will need to address the issues covered in the special controls guidance. The firm must show in its 510(k) that its device meets the requirements of 21 CFR 807.87 and complies with the special controls, either by following the recommendations of the special controls guidance or, in some other way, providing equivalent assurances of safety and effectiveness. Manufacturers who follow the specific measures recommended to address the issues identified in the special controls guidance will be able to market their devices without being subject to the premarket notification requirements of section 510(k) of the act, subject to the limitations of § 870.9. Manufacturers who choose alternative means to address one or more of the issues identified in the special controls guidance will remain subject to the premarket notification requirements of section 510(k) and must obtain marketing clearance for their device.

VII. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VIII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is not a significant regulatory action as defined by the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA believes that manufacturers are already substantially in compliance with the recommendations in the draft guidance document and exemption from the premarket notification requirements for devices following the specific measures recommended in the special control will simplify the entry to market for other manufacturers, including small manufacturers, the agency certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $122 million, using the most current (2005) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this proposed rule to result in any 1-year expenditure that would meet or exceed this amount.

IX. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would have substantial direct effects on the States, on the relationship between the National Government and

the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has tentatively concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement has not been prepared.

X. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520) is not required.

FDA also tentatively concludes that the draft special control guidance document does not contain new information collection provisions that are subject to review and clearance by OMB under the PRA. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the draft guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes;'' the notice contains an analysis of the paperwork burden for the draft guidance.

XI. 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.

List of Subjects in 21 CFR Part 870

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 870 be amended as follows:

PART 870—CARDIOVASCULAR DEVICES

1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

2. In § 870.2360, paragraph (b) is revised to read as follows:

§ 870.2360 Electrocardiograph electrode.

* * * * *

(b) *Classification.* Class II (special controls). The special control for the device is FDA's guidance document entitled ''Class II Special Controls Guidance Document: Electrocardiograph Electrodes.'' See § 870.1(e) for the availability of this guidance document. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 870.9, if it addresses the issues identified in the special controls guidance by following the specific measures recommended in the special controls guidance.

Dated: September 26, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E7–19580 Filed 10–3–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 301

[REG–149036–04]

RIN 1545–BG75

Application of Section 6404(g) of the Internal Revenue Code Suspension Provisions; Hearing

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Cancellation of notice of public hearing on proposed rulemaking.

SUMMARY: This document cancels a public hearing on proposed regulations for the suspension of interest, penalties, additions to tax, or additional amounts under section 6404(g) of the Internal Revenue Code. The proposed regulations explain the general rules for suspension as well as exceptions to those general rules.

DATES: The public hearing, originally scheduled for October 11, 2007, at 10 a.m., is cancelled.

FOR FURTHER INFORMATION CONTACT: Richard A. Hurst of the Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration), at *Richard.A.Hurst@irscounsel.treas.gov.*

SUPPLEMENTARY INFORMATION: A notice of public hearing that appeared in the **Federal Register** on Thursday, June 21, 2007 (72 FR 34199), announced that a public hearing was scheduled for October 11, 2007, at 10 a.m., in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. The subject of the public hearing is under section 6404(g) of the Internal Revenue Code.

The public comment period for these regulations expired on September 19, 2007. The notice of proposed rulemaking and notice of public hearing instructed those interested in testifying at the public hearing to submit a request to speak and an outline of the topics to be addressed. As of Friday, September 21, 2007, no one has requested to speak. Therefore, the public hearing scheduled for October 11, 2007, is cancelled.

LaNita Van Dyke,

Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. E7–19570 Filed 10–3–07; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF JUSTICE

28 CFR Part 16

[AAG/A Order No. 034–2007]

Privacy Act of 1974; Implementation

AGENCY: Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Bureau of Investigation (FBI), a component agency of the Department of Justice (DOJ), proposes to exempt a new Privacy Act system of records entitled Law Enforcement National Data Exchange (N-DEx) from certain provisions of the Privacy Act. As explained in the proposed rule, the exemption is necessary to avoid interference with the law enforcement functions and responsibilities of the FBI and the N-DEx system. Public comment is invited.

DATES: Comments must be received by November 13, 2007.

ADDRESSES: Address all comments to Joo Chung, Counsel, Privacy and Civil Liberties Office, Office of the Deputy Attorney General, 950 Pennsylvania Avenue, NW., Washington, DC 20530, or facsimile 202–616–9627. To ensure proper handling, please reference the AAG/A Order No. in your correspondence. You may review an electronic version of the proposed rule at *http://www.regulations.gov.* You may also comment via the Internet to the Privacy and Civil Liberties Office at *DOJPrivacy ACTProposedRegulations@usdoj.gov;* or by using the comment form for this regulation at *http://www.regulations.gov.* Please include the AAG/A Order No. in the subject box.