

delay due to heightened security precautions.

The FTC Act and other laws the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives, whether filed in paper or electronic form. Comments received will be available to the public on the FTC website, to the extent practicable, at (<http://www.ftc.gov/os/publiccomments.shtml>). As a matter of discretion, the Commission makes every effort to remove home contact information for individuals from the public comments it receives before placing those comments on the FTC website. More information, including routine uses permitted by the Privacy Act may be found in the FTC's privacy policy, at (<http://www.ftc.gov/ftc/privacy.shtml>).

Section V. Communications by Outside Parties to Commissioners or Their Advisors

Written communications and summaries of transcripts of oral communications respecting the merits of this proceeding from any outside party to any Commissioner or Commissioner's advisor will be placed on the public record.⁵

List of Subjects in 16 CFR Part 312

Children, Communications, Consumer protection, Electronic mail, E-mail, Internet, Online service, Privacy, Record retention, Safety, Science and technology, Trade practices, Website, Youth.

Authority: 15 U.S.C. §§ 6501-6508.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2010-7549 Filed 4-2-10; 10:31 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 882 and 890

[Docket No. FDA-2009-N-0493]

RIN 0910-ZA37

Neurological and Physical Medicine Devices; Designation of Special Controls for Certain Class II Devices and Exemption From Premarket Notification

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend certain neurological device and physical medicine device regulations to establish special controls for these class II devices and to exempt some of these devices from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of draft guidance documents that would serve as special controls for each of these devices if the rule is finalized.

DATES: Submit written or electronic comments by July 6, 2010. See section III 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. FDA-2009-N-0493 and/or RIN number 0910-ZA37, by any of the following methods:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.

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.

Instructions: All submissions must include the agency name and docket number and Regulatory Information Number (RIN) (if a RIN number has been assigned) for this rulemaking. All comments will be posted without change to <http://www.regulations.gov>, 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.regulations.gov> and insert the docket number, 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:

Robert J. DeLuca, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. G214, Silver Spring, MD 20993-0002, e-mail: Robert.DeLuca@fda.hhs.gov, 301-796-6630.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authority

The Federal Food, Drug, and Cosmetic Act (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 Device Amendments (SMDA) (Public Law 101-629), and the Food and Drug Administration Modernization Act (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).

Most generic types of devices that were on the market before the date of the 1976 amendments (May 28, 1976) (generally referred to as preamendments devices) have been classified by FDA under the procedures set forth in section 513(c) and (d) of the act through the issuance of classification regulations into one of these three regulatory classes. Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as postamendments devices) are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the

⁵ See 16 CFR Part 1.26(b)(5).

act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that is already legally marketed. The agency determines whether new devices are substantially equivalent to predicate devices through review of premarket notifications under section 510(k) of the act (21 U.S.C. 360(k)). Section 510(k) of the act and the implementing regulations, part 807 (21 CFR part 807), require persons who intend to market a new device to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is "substantially equivalent" within the meaning of section 513(i) of the act to a legally marketed device that does not require premarket approval.

Section 510(m)(2) of the act provides that FDA may exempt a device from the premarket notification requirement on its own initiative or upon petition of an interested person, if FDA determines that a 510(k) is not necessary to provide reasonable assurance of 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, or of the petition, and to provide a 30-day comment period. Within 120 days of publication of this document, FDA must publish in the **Federal Register** its final determination regarding the exemption of the device that was the subject of the notice.

II. The Proposed Rule

A. Establishment of Special Controls

Under section 513(a)(1)(B) of the act, as amended by SMDA, class II devices are defined as devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. Special controls may include the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the agency deems necessary to provide such assurance (21 CFR 860.3(c)(2)).

Consistent with this authority, FDA is proposing to amend the neurological devices regulations to establish special controls for electroconductive media (§ 882.1275 (21 CFR 882.1275)) and the cutaneous electrode (§ 882.1320 (21 CFR 882.1320)). FDA is also proposing to amend the neurological devices regulation at § 882.5890 (21 CFR 882.5890) to add paragraphs for the

transcutaneous electrical nerve stimulator for pain relief (§ 882.5890(a)), the transcutaneous electrical nerve stimulator for pain relief intended for over the counter use (§ 882.5890(b)), the transcutaneous electrical nerve stimulator with limited output for pain relief (§ 882.5890(c)), the percutaneous electrical nerve stimulator for pain relief (§ 882.5890(d)), the transcutaneous electrical stimulator for aesthetic purposes (§ 882.5890(e)), and the transcutaneous electrical stimulator with limited output for aesthetic purposes (§ 882.5890(f)).

Similarly, FDA is proposing to amend the physical medicine devices regulation at § 890.5850 (21 CFR 890.5850) to add paragraphs for the powered muscle stimulator for rehabilitation (§ 890.5850(a)), the powered muscle stimulator with limited output for rehabilitation (§ 890.5850(b)), the powered muscle stimulator for muscle conditioning (§ 890.5850(c)), and the powered muscle stimulator with limited output for muscle conditioning (§ 890.5850(d)). FDA believes that subdividing the classification regulations for each of these device types would provide clarity for persons referencing the classification regulation.

FDA is also proposing to establish special controls for each of these device types. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of availability of the following draft guidance documents that would serve as special controls:

(1) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Electroconductive Media;

(2) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Cutaneous Electrode;

(3) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief;

(4) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use;

(5) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief;

(6) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes;

(7) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited Output for Aesthetic Purposes;

(8) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation;

(9) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation;

(10) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning; and

(11) Draft Guidance for Industry and FDA Staff; Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning.

The agency believes that the applicable special controls and general controls will provide reasonable assurance of the safety and effectiveness for each of the foregoing device types.

B. Exemption From Premarket Notification Requirements

Together with the establishment of special controls, FDA, on its own initiative, is also proposing to exempt some of these device types from premarket notification, subject to limitations. FDA may consider a number of factors in determining whether premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of a class II device. These factors are discussed in the guidance the agency issued on February 19, 1998, entitled "Procedures for Class II Device Exemptions from Premarket Notification, Guidance for Industry and CDRH Staff." The guidance can be obtained electronically at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080198.htm>.

FDA believes that the following class II devices are appropriate for exemption from premarket notification, subject to the limitations of exemptions identified in §§ 882.9 and 890.9 (21 CFR 882.9 and 890.9), because the applicable special controls and general controls provide reasonable assurance of safety and effectiveness if device manufacturers follow the special controls guidances' recommendations and, for the transcutaneous electrical nerve stimulator with limited output for pain relief and the powered muscle stimulator with limited output for rehabilitation, if the devices are also restricted to sale, distribution, and use

in accordance with the prescription device requirements in § 801.109 (21 CFR 801.109):

- Electroconductive media (§ 882.1275);
- Cutaneous electrode (§ 882.1320);
- Transcutaneous electrical nerve stimulator with limited output for pain relief (§ 882.5890(c));
- Transcutaneous electrical stimulator with limited output for aesthetic purposes (§ 882.5890(e));
- Powered muscle stimulator with limited output for rehabilitation (§ 890.5850(b)); and
- Powered muscle stimulator with limited output for muscle conditioning (§ 890.5850(d)).

FDA is inviting comment on these proposed exemptions.

FDA advises that exemption from the requirement of premarket notification does not mean that these devices would be exempt from any other statutory or regulatory requirements, unless such exemption is explicitly provided by order or regulation. Indeed, FDA's proposal to exempt these device types from the requirement of premarket notification is based, in part, on the assurance of safety and effectiveness that other regulatory controls, such as current good manufacturing practice requirements (21 CFR part 820), provide.

III. 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 applicable device types will need to address the issues covered in the respective special controls guidances. Unless otherwise exempt, the firm must show in its 510(k) that its device meets the requirements of § 807.87 and complies with the special controls.

As discussed previously in this document, if the rule is finalized, for six of the device types, manufacturers who follow the specific measures recommended to address the issues identified in the special controls guidances would 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 §§ 882.9 and 890.9. Manufacturers of two of these six device types, transcutaneous electrical nerve stimulator with limited output for pain relief and powered muscle stimulator

with limited output for rehabilitation, would also be restricted to sale, distribution, and use in accordance with the prescription device requirements in § 801.109 in order to be able to market their devices without being subject to premarket notification. Manufacturers who choose alternative means to address one or more of the issues identified in the applicable special controls guidance would remain subject to the premarket notification requirements of section 510(k) and would need to obtain marketing clearance for their device.

IV. 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.

V. 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. Classification of the devices discussed in this proposed rule into class II with special controls will simplify the process of bringing these devices to market. In addition, exemption from the premarket notification requirements for six of these devices would reduce the costs associated with bringing the devices to market. Thus, the agency proposes to certify that the final 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 \$133 million, using the most current (2008) 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.

The special controls required by this proposed rule for the 11 listed devices do not impose significant costs because they do not add new regulatory requirements. Instead, the special controls clarify FDA expectations and should shorten the time to market for some new or modified devices. Manufacturers of devices exempt from the premarket notification requirements would no longer have to wait until they receive a substantial equivalence determination from FDA before marketing the device. For manufacturers of devices that still require premarket notification, the special controls clarify FDA's expectations making compliance with the general and special controls more straightforward and should shorten the time to prepare a submission and for FDA review. Moreover, manufacturers of devices that become exempt from the premarket notification requirement would also benefit from the elimination of application preparation time and of paper, copying, and mailing costs by not having to prepare and submit 510(k)s. These application savings are negligible, however, relative to the total cost of bringing a medical device to market.

The sector of the device industry covered by the proposed rule is part of the Electromedical and Electrotherapeutic Apparatus Manufacturing sector, NAICS code 334510. The Small Business Administration classifies firms in this sector as small if they have fewer than 500 employees. About 90 percent of firms in this sector are small, employing about 25 percent of the sector's work force. Table 1 lists the number of manufacturers for the different types of devices, an estimate of the number of 510(k)s submitted each year (based on historical ranges), and our best estimate of the percentage of new devices that would be exempt from the premarket notification requirement for each type of device.

TABLE 1.—NUMBER OF MANUFACTURERS AND 510(K)S PER YEAR

Device Type	No. of Manufacturers ¹	No. of 510(k)s per Year ²	Percentage Exempt
Electroconductive media	21	0-5	>90%
Cutaneous electrode	76	5-15	>90%
Transcutaneous electrical nerve stimulator for pain relief	110	15-25	60%
Transcutaneous electrical stimulator for aesthetic purposes	4	0-5	60%
Powered muscle stimulator for rehabilitation	81	10-20	50%
Powered muscle stimulator for muscle conditioning	12	0-8	50%

¹ Manufacturers make multiple device types.

² Data from 2000–2009.

The potential impact on small firms would be to reduce the cost of entry by shortening the time to market for those firms who plan to market these devices. It will impose no additional regulatory burden on small entities, and it may permit some small potential competitors to enter the marketplace by lowering their costs. Therefore the agency proposes to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

VI. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. Section 4(a) of the Executive order requires agencies to “construe * * * a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State law conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different from or in addition to” certain federal requirements applicable to devices (21 U.S.C. 360k; See *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic*, 128 S. Ct. 999 (2008)). If this proposed rule is made final, the special controls

established by the final rule would create “requirements” for specific medical devices under 21 U.S.C. 360k, even though product sponsors have some flexibility in how they meet those requirements (*Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–742 (9th Cir. 1997)).

VII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no new collection of information; however, consistent with the regulatory impact analysis in section V of this document, we anticipate that the exemption of 6 device types from the premarket notification requirements of the act will result in a reduction in burden to existing collections of information currently approved under OMB control number 0910–0120.

Accordingly, with respect to the collection of information discussed below, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

This proposed rule designates guidance documents and other special controls for certain neurological and physical medicine devices and exempts certain of these devices from premarket notification requirements. FDA expects an overall reduction in burden hours for manufacturers of the six device types that FDA is proposing to exempt from the premarket notification reporting requirements. The current burden associated with submitting a premarket notification submission under part 807, subpart E is 79 hours per submission at a cost of \$100 per hour resulting in a total cost of \$7,900 per submission. As identified elsewhere in this document, the six device types being exempted from the premarket notification requirements of the act will no longer be subject to this burden. Based on FDA’s estimates of annual premarket notifications submitted for the exempted device types (table 2 of this document), FDA estimates a total burden reduction of 34.25 annual premarket notification submissions (90% of 2.5)+(90% of 10)+(60% of 20)+(60% of 2.5)+(50% of 15)+(50% of 4), 2,706 hours (34.25 submissions x 79 hours), and \$270,600 (2,706 hours x \$100 hourly rate).

TABLE 2.—AVERAGE NUMBER OF MANUFACTURERS AND PREMARKET NOTIFICATIONS (510(K)S) PER YEAR FOR PROPOSED EXEMPT DEVICE TYPES

Device Type	No. of Manufacturers ¹	No. of 510(k)s per Year ²	Percentage Exempt
Electroconductive media	21	2.5	> 90%
Cutaneous electrode	76	10	> 90%
Transcutaneous electrical nerve stimulator for pain relief	110	20	60%
Transcutaneous electrical stimulator for aesthetic purposes	4	2.5	60%

TABLE 2.—AVERAGE NUMBER OF MANUFACTURERS AND PREMARKET NOTIFICATIONS (510(K)S) PER YEAR FOR PROPOSED EXEMPT DEVICE TYPES—Continued

Device Type	No. of Manufacturers ¹	No. of 510(k)s per Year ²	Percentage Exempt
Powered muscle stimulator for rehabilitation	81	15	50%
Powered muscle stimulator for muscle conditioning	12	4	50%

¹Manufacturers make multiple device types.

²Data averaged from 2000–2009.

The guidance documents designated as special controls for each of these 11 device types do not impose significant costs because they do not add new regulatory requirements. Instead, the special controls clarify FDA expectations and should shorten the time to market for some new or modified devices. For manufacturers of devices that still require premarket notification, the special controls clarify FDA's expectations making compliance with the general and special controls more straightforward and should shorten the time to prepare a submission and for FDA review. While this clarification in expectations may reduce the actual burden associated with submitting a premarket notification submission for these specific device types, this reduction is negligible when accounting for the size of entire premarket notification program. Accordingly, FDA will not be adjusting the per submission burden estimate of 79 hours for premarket notification submissions accounted for under OMB control number 0910–0120.

VIII. 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 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

21 CFR Part 882

Medical devices, Neurological devices.

21 CFR Part 890

Medical devices, Physical medicine 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 parts 882 and 890 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 21 CFR part 882 continues to read as follows:

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

2. Section 882.1275 is amended by revising paragraph (b) to read as follows:

§ 882.1275 Electroconductive media.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Electroconductive Media.” See § 882.1(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 § 882.9, when it follows the recommendations of the special controls guidance.

3. Section 882.1320 is amended by revising paragraph (b) to read as follows:

§ 882.1320 Cutaneous electrode.

* * * * *

(b) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Cutaneous Electrode.” See § 882.1(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 § 882.9, when it follows the recommendations of the special controls guidance.

4. Section 882.5890 is revised to read as follows:

§ 882.5890 Transcutaneous electrical nerve stimulator for pain relief.

(a) *Transcutaneous electrical nerve stimulator for pain relief—(1) Identification.* A transcutaneous electrical nerve stimulator for pain relief is an electrically powered device used to apply an electrical current to electrodes on a patient's skin to relieve pain. This does not include the device

types classified in paragraphs (b) through (f) of this section.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) The FDA guidance document entitled “Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief.” See § 882.1(e) for the availability of this guidance document; and

(ii) Sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter.

(b) *Transcutaneous electrical nerve stimulator for pain relief intended for over-the-counter use—(1) Identification.* A transcutaneous electrical nerve stimulator for pain relief intended for over-the-counter use is an electrically powered device intended for over-the-counter use and used to apply an electrical current to electrodes on a patient's skin to relieve pain. This does not include the device types classified in paragraphs (a) and (c) through (f) of this section.

(2) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use.” See § 882.1(e) for the availability of this guidance document.

(c) *Transcutaneous electrical nerve stimulator with limited output for pain relief—(1) Identification.* A transcutaneous electrical nerve stimulator with limited output for pain relief is an electrically powered device that is used to apply an electrical current to electrodes on a patient's skin to relieve pain. This does not include the device types classified in paragraphs (a) through (b) and (d) through (f) of this section. The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:

(i) A maximum charge per phase that does not exceed Q, where $Q = 20 +$

(28)(t) microcoulombs (and where t is the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);

(ii) A maximum average current that does not exceed 10 milliamperes (average absolute value);

(iii) A maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;

(iv) An average direct current (dc) that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;

(v) A maximum current density that does not exceed 2 milliamperes root mean square (rms) per square centimeter of electrode conductive surface area; and

(vi) A maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) The FDA guidance document entitled “Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief.” See § 882.1(e) for the availability of this guidance document; and

(ii) Sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations of exemptions in § 882.9, when it follows the recommendations of the special controls guidance and its sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter.

(d) *Percutaneous electrical nerve stimulator for pain relief—(1) Identification.* A percutaneous electrical nerve stimulator for pain relief is an electrically powered device used to apply an electrical current to electrodes that pass through a patient’s skin to relieve pain. This does not include the device types classified in paragraphs (a) through (c) and (e) through (f) of this section.

(2) *Classification.* Class II (special controls). The special control for this device is restriction of sale, distribution, and use to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter.

(e) *Transcutaneous electrical stimulator for aesthetic purposes—(1) Identification.* A transcutaneous

electrical stimulator for aesthetic purposes is an electrically powered device applied externally to the body surface using cutaneous electrodes to deliver electrical current into the body, and is intended to achieve aesthetic effects through physical change to the structure of the body. This does not include the device types classified in paragraphs (a) through (d) and (f) of this section.

(2) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes.” See § 882.1(e) for the availability of this guidance document.

(f) *Transcutaneous electrical stimulator with limited output for aesthetic purposes—(1) Identification.* A transcutaneous electrical stimulator with limited output for aesthetic purposes is an electrically powered device that is applied externally to the body surface using cutaneous electrodes to deliver electrical current into the body, and is intended to achieve aesthetic effects through physical change to the structure of the body. This does not include the device types classified in paragraphs (a) through (e) of this section. The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:

(i) A maximum charge per phase that does not exceed Q, where $Q = 20 + (28)(t)$ microcoulombs (and where t is the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);

(ii) A maximum average current that does not exceed 10 milliamperes (average absolute value);

(iii) A maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;

(iv) An average dc that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;

(v) A maximum current density that does not exceed 2 milliamperes rms per square centimeter of electrode conductive surface area; and

(vi) A maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.

(2) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled “Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited

Output for Aesthetic Purposes.” See § 882.1(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 of exemptions in § 882.9, when it follows the recommendations of the special controls guidance.

PART 890—PHYSICAL MEDICINE DEVICES

5. The authority citation for 21 CFR part 890 continues to read as follows:

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

6. Section 890.5850 is revised to read as follows:

§ 890.5850 Powered muscle stimulator.

(a) *Powered muscle stimulator for rehabilitation—(1) Identification.* A powered muscle stimulator for rehabilitation is an electrically powered device intended for medical purposes that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes contacting the affected body area. This does not include the powered muscle stimulators classified in paragraphs (b) through (d) of this section.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) The FDA guidance document entitled “Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation.” See § 890.1(e) for the availability of this guidance document; and

(ii) Sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter.

(b) *Powered muscle stimulator with limited output for rehabilitation—(1) Identification.* A powered muscle stimulator with limited output for rehabilitation is an electrically powered device that is intended for medical purposes, and repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes contacting the affected body area. This does not include the powered muscle stimulators classified in paragraphs (a), (c), and (d) of this section. The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:

(i) A maximum charge per phase that does not exceed Q, where $Q = 20 + (28)(t)$ microcoulombs (and where t is

the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);

(ii) A maximum average current that does not exceed 10 milliamperes (average absolute value);

(iii) A maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;

(iv) An average direct current (dc) that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;

(v) A maximum current density that does not exceed 2 milliamperes root mean square (rms) per square centimeter of electrode conductive surface area; and

(vi) A maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.

(2) *Classification.* Class II (special controls). The special controls for this device are:

(i) The FDA guidance document entitled "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation." See § 890.1(e) for the availability of this guidance document; and

(ii) Sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations of exemptions in § 890.9, when it follows the recommendations of the special controls guidance and its sale, distribution, and use are restricted to prescription use in accordance with the prescription device requirements in § 801.109 of this chapter.

(c) *Powered muscle stimulator for muscle conditioning—(1) Identification.* A powered muscle stimulator for muscle conditioning is an electrically powered device that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes and into the body, thereby temporarily affecting the stimulated muscles' contractile properties, force output, and/or fatigue resistance. This does not include the powered muscle stimulators classified in paragraphs (a), (b), and (d) of this section.

(2) *Classification.* Class II (special controls.) The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning." See § 890.1(e) for the availability of this guidance document.

(d) *Powered muscle stimulator with limited output for muscle conditioning—(1) Identification.* A powered muscle stimulator with limited output for muscle conditioning is an electrically powered device that repeatedly contracts muscles by passing pulsed electrical current through cutaneous electrodes and into the body, thereby temporarily affecting the stimulated muscles' contractile properties, force output, and/or fatigue resistance. This does not include the powered muscle stimulators classified in paragraphs (a) through (c) of this section. The device utilizes a stimulus generator that delivers, into a resistive load, which represents the worse case of either 500 ohms or the typical load expected during normal conditions of use, the following:

(i) A maximum charge per phase that does not exceed Q, where $Q = 20 + (28)t$ microcoulombs (and where t is the phase duration expressed in milliseconds and measured at 50 percent of the phase amplitude);

(ii) A maximum average current that does not exceed 10 milliamperes (average absolute value);

(iii) A maximum primary (depolarizing) phase duration that does not exceed 500 microseconds;

(iv) An average dc that does not exceed 100 microamperes when no pulses are being applied, or if the device fails;

(v) A maximum current density that does not exceed 2 milliamperes rms per square centimeter of electrode conductive surface area; and

(vi) A maximum average power density that does not exceed 0.25 watts per square centimeter of electrode conductive surface area.

(2) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning." See § 890.1(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 of exemptions in § 890.9, when it follows the recommendations of the special controls guidance.

Dated: March 24, 2010.

Jeffrey Shuren,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG-2010-0180]

RIN 1625-AA08

Special Local Regulation for Marine Event; Temporary Change of Dates for Recurring Marine Event in Fifth Coast Guard District

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to temporarily change the enforcement period of special local regulations for recurring marine events in Fifth Coast Guard District. The regulation applies to one recurring marine event that establishes two spectator vessel anchorage areas and restricts vessel traffic. Special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in portions of the Hampton River, Hampton, VA, and Sunset Creek, Hampton, VA during the event.

DATES: Comments and related material must be received by the Coast Guard on or before May 5, 2010.

ADDRESSES: You may submit comments identified by docket number USCG-2010-0180 using any one of the following methods:

(1) *Federal eRulemaking Portal:* <http://www.regulations.gov>.

(2) *Fax:* 202-493-2251.

(3) *Mail:* Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590-0001.

(4) *Hand Delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202-366-9329.

To avoid duplication, please use only one of these four methods. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section below for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions on this proposed rule, call or e-mail LT Tiffany Duffy, Project Manager, Sector Hampton Roads, Waterways Management Division, Coast Guard; telephone 757-668-5580, e-mail