

LUSEDRA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

**ADDRESSES:** Submit written comments and petitions 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.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6222, Silver Spring, MD 20993-0002, 301-796-3602.

**SUPPLEMENTARY INFORMATION:** The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product LUSEDRA (fospropofol disodium). LUSEDRA is a sedative-hypnotic agent indicated for monitored anesthesia care sedation in

adult patients undergoing diagnostic or therapeutic procedures. Subsequent to this approval, the Patent and Trademark Office received patent term restoration applications for LUSEDRA (U.S. Patent Nos. 6,204,257 and 6,872,838) from University of Kansas, and the Patent and Trademark Office requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated September 29, 2009, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of LUSEDRA represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for LUSEDRA is 2,405 days. Of this time, 1,962 days occurred during the testing phase of the regulatory review period, while 443 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective:* May 15, 2002. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on May 15, 2002.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the act:* September 27, 2007. FDA has verified the applicant's claim that the new drug application (NDA) 22-244 was submitted on September 27, 2007.

3. *The date the application was approved:* December 12, 2008. FDA has verified the applicant's claim that NDA 22-244 was approved on December 12, 2008.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 1,424 days of patent term extension for patent no. 6,204,257 and 899 days of patent term extension for patent no. 6,872,838.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 4, 2010. Furthermore, any interested person may

petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by October 4, 2010. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, 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. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 22, 2010.

**Jane A. Axelrad,**

*Associate Director for Policy, Center for Drug Evaluation and Research.*

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**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-D-0495]

#### Draft Guidance for Industry and Food and Drug Administration Staff; Medical Devices; Neurological and Physical Medicine Device Guidance Documents; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of draft special controls guidance documents for 11 neurological and physical medicine devices. FDA has developed a draft special controls guidance document for each of the 11 devices. These draft guidance documents describe a means by which these devices 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 special controls for each of these devices and would exempt six of them from the premarket notification requirements of the Federal Food, Drug, and Cosmetic Act (the act). These draft guidance documents are not final nor are they in effect at this time.

**DATES:** Although you can comment on any guidance documents at any time

(see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on any of these draft guidances before it begins work on the final versions of the guidances, submit written or electronic comments by July 6, 2010.

**ADDRESSES:** Submit written requests for single copies of any or all of the draft guidance documents to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4617, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance documents.

Submit written comments concerning any of the draft guidance documents 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.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**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](mailto:Robert.DeLuca@fda.hhs.gov), 301-796-6630.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of the following 11 draft guidance documents:

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

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

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

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

(5) "Class II Special Controls Guidance Document: Transcutaneous

Electrical Nerve Stimulator with Limited Output for Pain Relief; Draft Guidance for Industry and FDA Staff";

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

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

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

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

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

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

Each draft special controls guidance document identifies the classification, product code, and classification identification for each of the respective 11 device types. In addition, they would serve as special controls that, when followed and combined with the general controls and any other applicable special controls, would generally address the risks associated with these devices.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate special controls for these devices. The rule also proposes to exempt the following six device types from premarket notification requirements if they follow the designated special controls, including addressing the issues identified in the special controls guidance documents by following the guidances' recommendations: (1) Electroconductive media; (2) cutaneous electrode; (3) transcutaneous electrical nerve stimulator with limited output for pain relief; (4) transcutaneous electrical stimulator with limited output for aesthetic purposes; (5) powered muscle stimulator with limited output for rehabilitation; and (6) powered muscle stimulator with limited output for muscle conditioning.

These draft guidance documents were developed to describe a means by which these devices may comply with the requirement of special controls for class

II devices. FDA believes that special controls, when combined with the general controls, would be sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

**II. Significance of Guidance**

These draft guidance documents are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). These draft guidances, when finalized will reflect the agency's current thinking regarding (1) Electroconductive media; (2) the cutaneous electrode; (3) the transcutaneous electrical nerve stimulator for pain relief; (4) the transcutaneous electrical nerve stimulator for pain relief intended for over the counter use; (5) the transcutaneous electrical nerve stimulator with limited output for pain relief; (6) the transcutaneous electrical stimulator for aesthetic purposes; (7) the transcutaneous electrical stimulator with limited output for aesthetic purposes; (8) the powered muscle stimulator for rehabilitation; (9) the powered muscle stimulator with limited output for rehabilitation; (10) the powered muscle stimulator for muscle conditioning; and (11) the powered muscle stimulator with limited output for muscle conditioning. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the applicable statute, regulations, or both.

**III. Electronic Access**

To receive any or all of the following 11 draft guidance documents 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(s) or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number to identify the guidance you are requesting: (1) "Class II Special Controls Guidance Document: Electroconductive Media; Draft Guidance for Industry and FDA Staff" (1571); (2) "Class II Special Controls Guidance Document: Cutaneous Electrode; Draft Guidance for Industry and FDA Staff" (1572); (3) "Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief; Draft Guidance for Industry and FDA Staff" (1573); (4) "Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use; Draft Guidance for Industry and FDA Staff" (1670); (5) "Class II Special Controls Guidance Document:

Transcutaneous Electrical Nerve Stimulator with Limited Output for Pain Relief; Draft Guidance for Industry and FDA Staff" (1574); (6) "Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator for Aesthetic Purposes; Draft Guidance for Industry and FDA Staff" (1575); (7) "Class II Special Controls Guidance Document: Transcutaneous Electrical Stimulator with Limited Output for Aesthetic Purposes; Draft Guidance for Industry and FDA Staff" (1576); (8) "Class II Special Controls Guidance Document: Powered Muscle Stimulator for Rehabilitation; Draft Guidance for Industry and FDA Staff" (1577); (9) "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Rehabilitation; Draft Guidance for Industry and FDA Staff" (1578); (10) "Class II Special Controls Guidance Document: Powered Muscle Stimulator for Muscle Conditioning; Draft Guidance for Industry and FDA Staff" (1579); and/or (11) "Class II Special Controls Guidance Document: Powered Muscle Stimulator with Limited Output for Muscle Conditioning; Draft Guidance for Industry and FDA Staff" (1580).

Persons interested in obtaining a copy of any or all of the draft guidance documents may also do so by using the Internet. 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/MedicalDevices/default.htm>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <http://www.regulations.gov>.

#### IV. Paperwork Reduction Act of 1995

These 11 draft guidance documents refer 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 part 807

(21 CFR part 807), subpart E pertain to premarket submission requirements for any person who intends to market certain medical devices, and have been approved under OMB control number 0910–0120.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a proposed rule that would designate special controls for each of these devices and would exempt six of them from the premarket notification requirements of the act. The proposed rule contains an analysis of the paperwork burden for the proposed rule, including the anticipated reduction in burden for manufacturers who follow the special controls and for manufacturers of the six proposed exempt device types. Consistent with the Paperwork Reduction Act of 1995, we solicit comment on our revised burden estimates.

#### V. Comments

The agency is specifically interested in comments on the types of claims appropriate for devices included within these 11 classifications and, for the devices that remain subject to premarket review, the data sponsors should submit to support those claims. For example, under the proposed rule, certain transcutaneous electrical stimulators for aesthetic purposes would remain subject to 510(k). The agency is interested in comments on the type of data sponsors should submit to show a transcutaneous electrical nerve stimulator device achieves "aesthetic effects through physical change to the structure of the body" as well as the predicate device does.

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 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 between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 24, 2010.

**Jeffrey Shuren,**

*Director, Center for Devices and Radiological Health.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2010–N–0100]

### Food Additives; Bisphenol A; Availability

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

**ACTION:** Notice; request for comment.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of five documents related to FDA's continuing assessment of Bisphenol A (BPA) and soliciting public comments on the four documents prepared by FDA's Center for Food Safety and Applied Nutrition (CFSAN). These documents do not represent an agency opinion or position on BPA, on which an interim update was recently provided. (See <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm>). Rather, these documents provide perspectives and opinions that are being considered by FDA as it continues its safety assessment of BPA. This action will enable FDA to consider comments from the public in its assessment of BPA for food contact applications.

**DATES:** Submit written or electronic information and comments by June 4, 2010.

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

**FOR FURTHER INFORMATION CONTACT:** Francis Lin, Center for Food Safety and Applied Nutrition (HFS–275), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1215.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

BPA is a chemical used in certain food contact materials. Uses of BPA were approved by FDA under its food additive regulations in the early 1960s. In recent years, questions have been raised about BPA's safety. On August 14, 2008, FDA delivered its Draft Assessment of BPA for Use in Food Contact Applications (the Draft Assessment) (Ref. 1) to a Subcommittee of FDA's Science Board for external review.

On September 16, 2008, the Subcommittee held a public meeting on BPA as part of its external review