Subpart N—[Amended]

■ 13. The authority citation for subpart N of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b); sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 14. Amend § 416.1400 by revising paragraph (b) to read as follows:

§ 416.1400 Introduction

* * * * *

(b) *Nature of the administrative review process.* In making a determination or decision in your case, we conduct the administrative review process in an informal, non-adversarial manner. Subject to the limitations on Appeals Council consideration of additional evidence (*see* §§ 416.1470(b) and 416.1476(b)), we will consider at each step of the review process any information you present as well as all the information in our records. You may present the information yourself or have someone represent you, including an attorney. If you are dissatisfied with our decision in the review process, but do not take the next step within the stated time period, you will lose your right to further administrative review and your right to judicial review, unless you can show us that there was good cause for your failure to make a timely request for review.

* * * * *

■ 15. Revise § 416.1435 to read as follows:

§ 416.1435 Submitting evidence prior to a hearing before an administrative law judge.

You should submit information or evidence as required by § 416.912 or any summary of the evidence to the administrative law judge with the request for hearing or within 10 days after filing the request, if possible. Each party shall make every effort to ensure that the administrative law judge receives all of the evidence (*see* § 416.912) or all of the evidence is available at the time and place set for the hearing.

Subpart O—[Amended]

■ 16. The authority citation for subpart O of part 416 continues to read as follows:

Authority: Secs. 702(a)(5), 1127, and 1631(d) of the Social Security Act (42 U.S.C. 902(a)(5), 1320a–6, and 1383(d)).

■ 17. In § 416.1540, revise paragraphs (b)(1) and (b)(2)(i) through (vii) to read as follows:

§ 416.1540 Rules of conduct and standards of responsibility for representatives.

* * * * *

(b) * * *

(1) Act with reasonable promptness to help obtain the information or evidence that the claimant must submit under our regulations, and forward the information or evidence to us for consideration as soon as practicable.

(2) * * *

(i) The claimant's medical source(s);

(ii) The claimant's age;

(iii) The claimant's education and training;

(iv) The claimant's work experience;

(v) The claimant's daily activities both before and after the date the claimant alleges that he or she became disabled;

(vi) The claimant's efforts to work; and

(vii) Any other factors showing how the claimant's impairment(s) affects his or her ability to work. In §§ 416.960 through 416.969a, we discuss in more detail the evidence we need when we consider vocational factors;

* * * * *

[FR Doc. 2014–03426 Filed 2–19–14; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2012–N–0378]

Physical Medicine Devices; Withdrawal of Proposed Effective Date of Requirement for Premarket Approval for Shortwave Diathermy for All Other Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the Agency issued in the **Federal Register** of July 6, 2012. In that document, FDA proposed to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the class III preamendment device, shortwave diathermy (SWD) for all other uses. In response to the requirements issued in the Food and Drug Administration Safety and Innovation Act (FDASIA) and new information received during a panel meeting, FDA is withdrawing the proposed rule and proposing a different action.

DATES: The proposed rule is withdrawn on February 20, 2014.

FOR FURTHER INFORMATION CONTACT: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1646, Silver Spring, MD 20993, 301–796–5616, *Melissa.Burns@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

In the **Federal Register** of July 6, 2012 (77 FR 39953), FDA issued a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the class III preamendments device, SWD for all other uses. This device applies electromagnetic energy to the body in the radio frequency bands that are currently identified as 13.56 megahertz or 27.12 megahertz and is intended for the treatment of medical conditions by means other than the generation of deep heat within body tissues (also referred to as nonthermal SWD). It is not intended for treatment of malignancies. The Agency also summarized its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA announced the opportunity for interested persons to request that the Agency change the classification of any of the aforementioned devices based on new information.

On July 9, 2012, FDASIA was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) (U.S.C. 360c(e)) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) changing the process for reclassifying a device from rulemaking to an administrative order. Subsequent to the publication of the proposed rule, FDASIA's amendments to section 513 of the FD&C Act required FDA to hold a classification panel (an FDA advisory committee) meeting on the classification of this device. On May 21, 2013, FDA held a meeting of the Orthopedic and Rehabilitation Devices Panel (the Panel), to discuss the classification of nonthermal SWD devices. There was panel consensus that although the effectiveness data were very limited, nonthermal SWD devices did not fit the regulatory definition of a class III device. Coupled with the rationale that special controls could be established to reasonably demonstrate an assurance of safety and effectiveness, the Panel recommended class II (special controls) for nonthermal SWD devices (Ref. 1).

II. Withdrawal of the Proposed Rule

FDA provided an opportunity for interested parties to comment on the proposed rule for SWD for all other uses (77 FR 39953, July 6, 2012). FDA received over 240 comments to the docket in response to the 2012 proposed rule. Comments that expressed an opinion about the classification of nonthermal SWD devices were usually in favor of a class II designation. Some comments did not openly state an opinion, but included arguments against the proposed rule that could reasonably be interpreted as support for a class II designation. There were also comments that agreed with a class III designation. In addition to the comments, FDA received five separate submissions to request a change in the classification of nonthermal SWD from class III to class II. In response to these comments and findings at the Panel meeting, FDA is withdrawing the proposed rule to call for PMAs for these devices and is proposing reclassification to class II (special controls).

III. Proposed Reclassification

Elsewhere in this issue of the **Federal Register**, FDA is proposing to reclassify SWD for all other uses, currently a preamendments class III device, into class II (special controls), and to rename the device ''nonthermal shortwave therapy.'' FDA continues to review the merits of the submissions for requests for reclassification that meet the requirements under 21 CFR 860.123, submitted in response to the proposed rule.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. FDA's Orthopedic and Rehabilitation Devices Panel transcript and other meeting materials are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/OrthopaedicandRehabilitationDevicesPanel/ucm352525.htm.*

Dated: February 13, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–03593 Filed 2–19–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA–2012–N–0378]

Physical Medicine Devices; Reclassification and Renaming of Shortwave Diathermy for All Other Uses

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed order; technical correction.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the shortwave diathermy (SWD) for all other uses, a preamendments class III device, into class II (special controls), and to rename the device ''nonthermal shortwave therapy (SWT).'' FDA is proposing this reclassification on its own initiative based on new information. FDA is also proposing a technical correction in the regulation for the carrier frequency for SWD and nonthermal SWT devices. This proposed action would implement certain regulatory requirements.

DATES: Submit either electronic or written comments on this proposed order by May 21, 2014. February 21, 2014FDA intends that SWD devices for all other uses must comply with the special controls and must submit a premarket notification (510(k)) within 60 days after the effective date of the final order. See Section XII for the proposed effective date of a final order based on this proposed order.

ADDRESSES: You may submit comments, identified by Docket No. FDA–2012–N–0378, 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 way:

- *Mail/Hand delivery/Courier (for paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Agency name and Docket No. FDA–2012–N–0378 for this rulemaking. All comments received may 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: Melissa Burns, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1646, Silver Spring, MD 20993, 301–796–5616, *Melissa.Burns@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), the Medical Devices Technical Corrections Act of 2004 (Pub. L. 108–214), the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), and the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, reflecting 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).

Section 513(a)(1) of the FD&C Act defines class II devices as those devices for which the general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but for which there is sufficient information to establish