DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket Nos. FDA–2011–N–0504 and FDA–2013–N–0195]

Neurological Devices; Withdrawal of Proposed Effective Date of Requirement for Premarket Approval for Cranial Electrotherapy Stimulator Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Withdrawal of proposed rule and proposed order.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing the proposed rule the Agency issued in the **Federal Register** of August 8, 2011, and the proposed order the Agency issued in the **Federal Register** of April 4, 2013, in part. In those documents, 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, cranial electrotherapy stimulator (CES). In response to information received in response to these two proposed actions, FDA is withdrawing the proposed rule and proposed order.

DATES: The proposed rule and the proposed order, in part, are withdrawn on June 12, 2014.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 August 8, 2011 (76 FR 48062), 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, CES. This device applies electrical current to a patient's head to treat insomnia, depression, or anxiety. 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.

In response to the proposed rule, FDA received three petitions conforming to the requirements of 21 CFR 860.123 requesting a change in the classification of CES devices. FDA referred the petitions to the Neurological Device Panel (''the Panel'') on February 10, 2011, for the Panel's recommendation on the requested change in classification (Ref. 1). The Panel recommended that the CES device for treatment of insomnia, depression, or anxiety should remain in class III requiring PMAs.

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) was enacted. Section 608(a) of FDASIA (126 Stat. 1056) amended section 513(e) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(e)), changing the process for reclassifying a device from rulemaking to an administrative order. Subsequently, on April 4, 2013 (78 FR 20268), FDA issued a proposed administrative order for several device types, including CES, to comply with the new procedural requirement created by FDASIA. This proposed order also proposed requiring filing of a PMA or a notice of completion of a PDP for the CES device.

II. Withdrawal of the Proposed Rule and Proposed Order

FDA provided an opportunity for interested parties to comment on the proposed rule and proposed order for CES devices (76 FR 48062, August 8, 2011, and 78 FR 20268, April 4, 2013). FDA received over 300 comments to the docket in response to the proposed rule and proposed order related to CES devices. Comments that expressed an opinion about the classification of CES 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 or order 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 four separate submissions to request a change in the classification of CES from class III to class II. FDA has considered the information before the Agency, including the deliberations of the February 10, 2012, Neurological Devices Panel and the reclassification petitions submitted for these devices, and has determined that there is sufficient information to establish special controls, and that these special controls, together with general controls, will provide a reasonable assurance of safety and effectiveness for CES devices. In this action, FDA is withdrawing the proposed rule and proposed order to call for PMAs for CES devices. FDA plans to issue a proposed order in the future for the reclassification of the CES device into class II. For the reasons described in this document, FDA is withdrawing the aforementioned proposed rule and proposed order.

III. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.* (FDA has verified the Web site address in this reference section, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

1. FDA's Neurological Devices Panel transcript and other meeting materials are available on FDA's Web site at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/NeurologicalDevicesPanel/ucm289361.htm.*

Dated: June 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13756 Filed 6–11–14; 8:45 am]

BILLING CODE 4164–01–P