Substances	Limitations
* * *	* * * *
Phosphorous acid, cyclic butylethyl propanediol, 2,4,6-tri-*tert*-butylphenyl ester (CAS Reg. No. 161717–32–4), which may contain not more than 1 percent by weight of triisopropanolamine (CAS Reg. No. 122–20–3).	For use only: 1. At levels not to exceed 0.2 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, and items 2.1, 2.2, or 2.3 (where the density of these polymers is not less than 0.94 gram per cubic centimeter), and items 3.1 or 3.2, provided that the finished polymer contacts foods of types I, II, and VI–B as described in Table I of § 176.170(c) of this chapter only under conditions of use B, C, D, E, F, G, and H as described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.1 percent by weight of olefin polymers complying with § 177.1520(c) of this chapter, items 1.1, 1.2, or 1.3, that contact food of types III, IV, V, VI–A, VI–C, VII, VIII, and IX as described in Table 1 of § 176.170(c) of this chapter, only under conditions of use C, D, E, F, and G as described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: May 15, 1997.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–14602 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. 93N–0027]

Neurological Devices; Effective Date of Requirement for Premarket Approval of Cranial Electrotherapy Stimulators

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revoke a regulation requiring that a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) be submitted for the cranial electrotherapy stimulator (CES), a medical device. This action is being taken in order that FDA may reconsider whether the CES device may be reclassified from class III (premarket approval) into class II (special controls) or class I (general controls). Elsewhere in this issue of the **Federal Register**, FDA is issuing an order requiring manufacturers of these devices to submit information concerning their safety and effectiveness.

EFFECTIVE DATE: July 7, 1997.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 4, 1979 (44 FR 51770), FDA published a final rule classifying the CES device into class III (premarket approval). This regulation was codified in § 882.5800 (21 CFR 882.5800). Section 882.5800 applies to: (1) Any CES that was in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (the amendments) (Pub. L. 94–295); and (2) any device that FDA has found to be substantially equivalent to the CES and that has been marketed on or after May 28, 1976.

In the **Federal Register** of August 31, 1993 (58 FR 45865), FDA published a proposed rule to require the filing of a PMA or a notice of completion of a PDP for the CES, under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)). In accordance with section 515(b)(2)(A) of the act, FDA included in the preamble to the proposal the agency's proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the act and the benefits to the public from the use of the device (58 FR 45865 at 45867). The primary concern expressed in the preamble to the proposed rule was the varying and contradictory results in investigations concerning the effectiveness of the CES device. FDA's conclusion at that time was that: ''FDA believes that CES's should undergo premarket approval to establish effectiveness for any intended use and to determine whether the benefits to the patient are sufficient to outweigh any risk'' (58 FR 45865 at 45868).

The August 31, 1993, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the agency's proposed findings. Under section 515(b)(2)(B) of the act, FDA also provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in the classification of the CES was required to be submitted by September 15, 1993. The comment period closed on November 1, 1993.

FDA received two petitions requesting a change in the classification of the device from class III to class II. FDA reviewed the petitions and found them to be deficient based on a lack of new information relevant to the device's classification. Each petitioner was sent a deficiency letter dated February 4, 1994, requesting a response to the reported deficiencies. Neither petitioner responded to the letter. Accordingly, the petitioners were notified on August 23, 1994, that the petitions were deemed closed.

In the **Federal Register** of August 24, 1995 (60 FR 43967), FDA issued a final rule to require the submission of a PMA or notice of completion of a PDP for the CES device. In that document, FDA also published a final order denying the petitions to reclassify the device. One PMA was submitted and filed for the

device. FDA has since become aware of additional information relevant to the possible reclassification of the CES device from class III to class II or class I. In the **Federal Register** of January 28, 1997 (62 FR 4023), FDA published a proposed rule to revoke the requirement that a PMA or a notice of completion of a PDP be filed for the CES device. FDA explained that it now believes that it is more appropriate to invoke the procedures under section 515(i) of the act for the device.

FDA provided an opportunity for interested persons to comment on the proposed rule. FDA received 41 comments. All but two of these comments directly supported the proposal to revoke the requirement that a PMA or notice of completion of a PDP be filed for the CES device. Many of the comments also requested that the CES device be reclassified into class I or II. Some comments submitted information in support of reclassification of the device. One comment included a paper addressing the government's role in regulating ''alternative medicine'' including, according to the comment, CES. Another comment submitted anecdotal information about a negative experience with CES but did not specifically take a position with respect to revocation of the requirement to submit a PMA. One comment supported the revocation of the requirement to submit a PMA, but suggested that FDA should, in all cases, issue an order under section 515(i) before it issues a proposed rule to require the submission of a PMA.

As noted above, elsewhere in this issue of the **Federal Register**, FDA is issuing an order under section 515(i) of the act to require manufacturers of CES devices to submit information to FDA about the safety and effectiveness of the devices. FDA will review all information submitted in response to that order and in the comments submitted on the proposed revocation to determine whether to reclassify the device.

In response to the suggestion that FDA not issue a rule under section 515(b) of the act without first issuing an order under section 515(i) of the act, as FDA previously stated in the **Federal Register** of May 6, 1994 (59 FR 23731), the Safe Medical Devices Act (SMDA) (Pub. L. 101–629) does not prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of the public health, independent of the procedure in section 515(i) of the act. FDA will consider the suggestion on a case-by-case basis.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under 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 this final rule will allow FDA to review information about these devices and determine the least burdensome degree of control needed to provide reasonable assurance of the safety and effectiveness of the CES device, the Commissioner of Food and Drugs certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects in 21 CFR Part 882

Medical devices.

Therefore under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

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

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 882.5800 is amended by revising paragraph (c) to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

* * * * *

(c) *Date a PMA or notice of completion of a PDP is required.* No effective date has been established of the requirement for premarket approval. See § 882.3.

Dated: May 28, 1997.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 97–14597 Filed 6–3–97; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

39 CFR Part 111

Domestic Mail Manual; Miscellaneous Amendments

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: This document describes the numerous amendments consolidated in the Transmittal Letter for Issue 52 of the Domestic Mail Manual, which is incorporated by reference in the Code of Federal Regulations, see 39 CFR 111.1. These amendments reflect changes in mail preparation requirements and other miscellaneous rules and regulations not previously published in the **Federal Register**.

EFFECTIVE DATE: July 1, 1997.

FOR FURTHER INFORMATION CONTACT: Neil Berger, (202) 268–2859.

SUPPLEMENTARY INFORMATION: The Domestic Mail Manual (DMM), incorporated by reference in title 39, Code of Federal Regulations, part 111, contains the basic standards of the U.S. Postal Service governing its domestic mail services; descriptions of the mail classes and special services and conditions governing their use; and standards for rate eligibility and mail preparation. The document is amended and republished about every 6 months, with each issue sequentially numbered.

DMM Issue 52, the next edition of the DMM, is scheduled for release on July 1, 1997. That issue will include substantive changes to the following special services: caller service, certified mail, Express Mail insurance, insured mail, post office box service, registered mail, return receipt, return receipt for merchandise, and special delivery. The final rule containing the standards for these changes was published on May 12, 1997, in the **Federal Register** (62 FR 26086–26098), as approved on May 5, 1997, by the Board of Governors to implement the Decision of the