Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a proposed 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).

DATES: Written comments by February 12, 1997. FDA intends that any final rule that may issue based on this proposal become effective on the date of its publication in the Federal Register.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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 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 (21 U.S.C. 360c(b)(2)(A)), 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' 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 Federal Register 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. Accordingly, FDA is proposing to revoke the August 24, 1995, final rule. Revocation of the final rule is necessary if FDA is to pursue possible reclassification of the device without a break in commercial distribution. This is because, under the August 24, 1995, final rule, devices which are not subject to an approved PMA on or before January 28, 1997, are deemed adulterated.

FDA believes that it is more appropriate to invoke the procedures under section 515(i) of the act for this device. Under that section, FDA would issue an order requiring manufacturers of CES devices to submit to FDA information concerning the safety and effectiveness of the device. FDA would then review the information submitted in response to this order and any other information available to FDA and determine whether to reclassify the device into class II or class I. If FDA were to decide not to reclassify the device, it would publish a new proposed rule under section 515(b) of the act to require the submission of PMA's.

II. Comments

Comments on the proposed revocation must be submitted by February 12, 1997. In accordance with 10.40(b)(2) (21 CFR 10.40(b)(2)). FDA has decided that there is good cause to shorten the usual comment period for the proposed revocation of the August 24, 1995, final rule for several reasons.

First, a longer comment period on the revocation is impracticable. In accordance with section 515(d)(1)(B)(i) of the act, the agency's decision to either approve or deny premarket approval

applications for this device must be issued no later than January 28, 1997. As long as the August 24, 1995, final rule remains in effect, devices not subject to approved premarket approval applications on that date would be adulterated under section 501(f)(1) of the act (21 U.S.C. 351(f)(1)). It is not possible for the agency to propose revocation of the August 24, 1995, final rule, offer a lengthy opportunity for comment on the proposed revocation, and issue a final revocation by January 28, 1997. Therefore, the agency has concluded that it is impracticable to offer a comment period of longer than 15 days on the proposed revocation of the August 24, 1995, final rule. Even with a shortened comment period, the agency will not be able to issue a final revocation prior to that date. Accordingly, the agency intends to exercise its enforcement discretion not to take regulatory action against the device during the short time it expects it will take to complete this rulemaking.

Second, a longer comment period would be contrary to the public interest. For the reasons discussed above, the agency has concluded that it is more appropriate to invoke the procedures in section 515(i) of the act for this device. It is possible that, as a result of those procedures, the device may be reclassified and not subject to premarket approval at all. A lengthy comment period would prevent the revocation from becoming effective in time to ensure continuity of regulation. Moreover, removal of the device from the market prior to full consideration of the information that would be obtained under section 515(i) of the act would cause great disruption to both users and manufacturers of the device and would have financial consequences. Therefore, the agency has concluded that it is in the public interest to shorten the comment period on this proposed revocation to 15 days.

Finally, the issues presented by the proposed revocation are, essentially, the same issues presented by the proposed rule to require premarket approval applications for this device. The agency received no comments expressing urgency that the device be subjected to premarket approval requirements. Further, the original classification panel recommended that the CES be considered a low priority for requiring premarket approval (43 FR 55640: November 28, 1978). FDA believes, therefore, that the shorter comment period will not deprive interested persons of the opportunity to express their views on the proposed revocation.

For the reasons discussed above, a comment period of longer than 15 days would be impracticable and contrary to the public interest. Therefore, FDA concludes that there is good cause for shortening the comment period on the proposed revocation of the August 24, 1995, final rule to 15 days.

III. 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.

IV. 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). 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 consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed 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 proposed rule, if finalized, 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 agency certifies that the proposed 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.

V. Request for Comments

Interested persons may, on or before February 12, 1997 submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments 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. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 882 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

1. The authority citation for 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 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: January 22, 1997.

Joseph A. Levitt,

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

[FR Doc. 97–1929 Filed 1–27–97; 8:45 am]

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DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 301

[REG–209803–95]

RIN 1545–AU08

Magnetic Media Filing Requirements for Information Returns; Hearing Cancellation

AGENCY: Internal Revenue Service, Treasury.

ACTION: Cancellation of notice of public hearing on proposed regulations.

SUMMARY: This document provides notice of cancellation of a public hearing on proposed Income Tax Regulations relating to the requirements for filing information returns on magnetic media or in other machine-readable form under section 6011(e) of the Internal Revenue Code.

DATES: The public hearing originally scheduled for Wednesday, February 5, 1997, beginning at 10:00 a.m. is cancelled.

FOR FURTHER INFORMATION CONTACT: Mike Slaughter of the Regulations Unit,