

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,

Assistant Chief Counsel (Corporate), (202) 622-7190, (not a toll-free number).

SUPPLEMENTARY INFORMATION: The subject of the public hearing is proposed regulations under section 6011(e) of the Internal Revenue Code. A notice of proposed rulemaking and notice of public hearing appearing in the Federal Register on Thursday, October 10, 1996 (61 FR 53161), announced that the public hearing on proposed regulations under section 6011 of the Internal Revenue Code would be held on Wednesday, February 5, 1997, beginning at 10:00 a.m., in the Commissioner's Conference Room, Room 3313, Internal Revenue Building, 1111 Constitution Avenue, NW, Washington, D.C.

The public hearing scheduled for Wednesday, February 5, 1997, is cancelled. Cynthia E. Grigsby, Chief, Regulations Unit Assistant Chief Counsel (Corporate).

[FR Doc. 97-2069 Filed 1-27-97; 8:45 am]
BILLING CODE 4830-01-U

FEDERAL MINE SAFETY AND HEALTH REVIEW COMMISSION

29 CFR Part 2704

Implementation of Equal Access to Justice Act in Commission Proceedings

AGENCY: Federal Mine Safety and Health Review Commission.

ACTION: Notice of proposed rulemaking; extension of comment period.

SUMMARY: The Federal Mine Safety and Health Review Commission previously published, on December 19, 1996 (61 FR 66961), proposed revisions to its rules providing for the award of attorneys' fees and other expenses under the Equal Access to Justice Act, 5 U.S.C. 504. The period for comments to the proposed rules was set to end on January 21, 1997. A request was made that the comment period be extended and the Commission has agreed to do so.

DATES: Comments should be received by February 3, 1997.

ADDRESSES: Comments should be sent to Richard L. Baker, Executive Director, Federal Mine Safety and Health Review Commission, 1730 K Street, NW, 6th Floor, Washington, DC 20006. For the convenience of persons who will be reviewing the comments, it is requested that commenters provide an original and three copies of their comments.

FOR FURTHER INFORMATION CONTACT: Norman M. Gleichman, General Counsel, Office of the General Counsel, 1730 K Street, NW, 6th Floor,

Washington, DC 20006, telephone: 202-653-5610 (202-566-2673 for TDD Relay). These are not toll-free numbers.

Issued this 22nd day of January, 1997 at Washington, D.C.

Mary Lu Jordan,

Chairman, Federal Mine Safety and Health Review Commission.

[FR Doc. 97-1945 Filed 1-27-97; 8:45 am]

BILLING CODE 6735-01-P-M

DEPARTMENT OF DEFENSE

Department of the Air Force

32 CFR Part 806b

[Air Force Reg. 12-35]

Air Force Privacy Act Program

AGENCY: Department of the Air Force, DOD.

ACTION: Proposed rule.

SUMMARY: The Department of the Air Force proposes to amend its Privacy Act regulations to add an exemption for a system of records identified as F111 AF JA B, Courts-Martial and Article 15 Records.

DATES: Comments must be received on or before March 31, 1997, to be considered by this agency.

ADDRESSES: Send comments to the Air Force Access Programs Manager, HQ USAF/SCMI, 1250 Air Force Pentagon, Washington, DC 20330-1250.

FOR FURTHER INFORMATION CONTACT: Ms. Anne Rollins at (703) 697-8674 or DSN 227-8674.

SUPPLEMENTARY INFORMATION: Executive Order 12866. It has been determined that this Privacy Act proposed rule for the Department of Defense does not constitute 'significant regulatory action'. Analysis of the rule indicates that it does not have an annual effect on the economy of \$100 million or more; does not create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; does not materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; does not raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866. Regulatory Flexibility Act. It has been determined that this Privacy Act proposed rule for the Department of Defense does not have significant economic impact on a substantial number of small entities because it is concerned only with the administration of Privacy Act systems of records within the Department of Defense. Paperwork Reduction Act. It has been determined that this Privacy Act

proposed rule for the Department of Defense imposes no information requirements beyond the Department of Defense and that the information collected within the Department of Defense is necessary and consistent with 5 U.S.C. 552a, known as the Privacy Act, and 44 U.S.C. Chapter 35.

List of subjects in 32 CFR part 806b Privacy.

Accordingly, 32 CFR part 806b is proposed to be amended as follows:

PART 806b - AIR FORCE PRIVACY ACT PROGRAM

1. The authority citation for 32 CFR Part 806b continues to read as follows:
Authority: Pub. L. 93-579, 88 Stat 1896 (5 U.S.C. 552a).

2. Appendix C to Part 806b is proposed to be amended by adding paragraph (b)(20) as follows:

Appendix C to Part 806b-General and specific exemptions.

* * * * *

b. *Specific exemptions.* * * *

(20) *System identifier and name:* F111 AF JA B, Courts-Martial and Article 15 Records.

(i) *Exemption.* Portions of this system of records may be exempt pursuant to 5 U.S.C. 552a(j)(2) from the following subsection of 5 U.S.C. 552a(c)(3), (c)(4), (d), (e)(1), (e)(2), (e)(3), (e)(4)(G), (H) and (I), (e)(5), (e)(8), (f), and (g).

(ii) *Exemption.* Portions of this system of records may be exempt pursuant to 5 U.S.C. 552a(k)(2) from the following subsection of 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H) and (I), and (f).

(iii) *Authority:* 5 U.S.C. 552a(j)(2) and (k)(2).

(iv) *Reason:* (1) From subsection (c)(3) because the release of the disclosure accounting, for disclosures pursuant to the routine uses published for this system, would permit the subject of a criminal investigation or matter under investigation to obtain valuable information concerning the nature of that investigation which will present a serious impediment to law enforcement.

(2) From subsection (c)(4) because an exemption is being claimed for subsection (d), this subsection will not be applicable.

(3) From subsection (d) because access to the records contained in this system would inform the subject of a criminal investigation of the existence of that investigation, provide the subject of the investigation with information that might enable him to avoid detection or apprehension, and would present a serious impediment to law enforcement.