Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: January 20, 1998.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set forth in the preamble, chapter III, part 404, subpart P of title 20 of the Code of Federal Regulations is amended as set forth below.

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Appendix 1 to subpart P of part 404 is amended by revising item 5 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

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5. Cardiovascular System (4.00 and 104.00): February 10, 2000.

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[FR Doc. 98–2276 Filed 1–29–98; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 97N–0133]

Revising the Announcement Procedures for Approvals and Denials of Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revise the premarket approval application (PMA) announcement procedure. FDA is discontinuing the publication of individual PMA approvals and denials in the **Federal Register**. Instead, the agency will announce approvals and denials of PMA's on the Internet. FDA will make the summaries of safety and effectiveness available through the Internet and by placing them in FDA's Dockets Management Branch. FDA will publish in the **Federal Register** for each quarter a list of the approvals and denials announced in that quarter. FDA is taking this action in order to expedite the availability of this information.

EFFECTIVE DATE: March 2, 1998.

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 December 12, 1980 (45 FR 81769 at 81772), FDA prescribed the contents of a PMA and the criteria for approving, disapproving, or withdrawing approval of a PMA. FDA acknowledged that, although the statute does not require it to publish the approval of a PMA in the **Federal Register**, section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) permits an interested person to obtain review of an approved PMA. Consequently, FDA proposed to announce approval of any PMA in the **Federal Register** and to include in the announcement notice of opportunity to petition for administrative review under section 515(g) of the act. (See 45 FR 81769 at 81772 and 81776). FDA also proposed to publish notice of any denial of approval or proposed withdrawal of approval of any PMA in the **Federal Register** and to include in the announcement notice of opportunity for administrative review under section 515(g) of the act. (See 45 FR 81769 at 81773 and 81777.) Subsequently, in the **Federal Register** of July 22, 1986 (51 FR 26342), FDA issued a final rule providing, among other things, that notice of approval of a PMA, notice of an order denying approval of a PMA, and notice of an order withdrawing approval of a PMA will be published in the **Federal Register**. (See 21 CFR 814.44(d), 814.45(d), and 814.46(e).) In the **Federal Register** of June 27, 1997 (62 FR 34680), FDA issued a proposed rule to revise the PMA announcement procedure by discontinuing publication of PMA approvals and denials in the **Federal Register** and, instead, announcing them on the Internet. Interested persons were given until September 25, 1997, to comment on the proposed regulation. FDA received two comments supporting the proposal, one from an in vitro diagnostic manufacturer and the other from a dental association.

II. Summary of the Final Rule

FDA is discontinuing publication of individual PMA approvals and denials in the **Federal Register**. Instead, FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet (http://www.fda.gov), by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of the PMA approvals and denials announced in that quarter.

FDA believes that this procedure will expedite public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than is the **Federal Register**.

In accordance with section 515(d)(3) of the act, notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515 (g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA will begin on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant, in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

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 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 selects 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 the final rule is consistent with 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 the final rule involves a minor procedural change that primarily affects FDA and has no direct effect on small companies, the agency 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.

V. Paperwork Reduction Act of 1995

This final rule contains no additional information collection requirements which are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (Pub. L. 104–13).

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for 21 CFR part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c-360j, 371, 372, 373, 374, 375, 379, 379e, 381.

2. Section 814.44 is amended by revising paragraph (d) to read as follows:

§ 814.44 Procedures for review of a PMA.

* * * * *

(d)(1) FDA will issue to the applicant an order approving a PMA if none of the reasons in § 814.45 for denying approval of the application applies. FDA will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft final labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed and upon the applicant submitting to FDA a copy of the final printed labeling before marketing. FDA will also give the public notice of the order, including notice of and opportunity for any interested persons to request review under section 515(d)(3) of the act. The notice of approval will be placed on FDA's home page on the Internet (http://www.fda.gov), and it will state that a detailed summary of information respecting the safety and effectiveness of the device, which was the basis for the order approving the PMA, including information about any adverse effects of the device on health, is available on the Internet and has been placed on public display, and that copies are available upon request. FDA will publish in the **Federal Register** after each quarter a list of the approvals announced in that quarter. When a notice of approval is published, data and information in the PMA file will be available for public disclosure in accordance with § 814.9.

(2) A request for copies of the current PMA approvals and denials document and for copies of summaries of safety and effectiveness shall be sent in writing to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

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3. Section 814.45 is amended by revising paragraph (d) to read as follows:

§ 814.45 Denial of approval of a PMA.

* * * * *

(d)(1) FDA will give the public notice of an order denying approval of the PMA. The notice will be placed on the FDA's home page on the Internet (http://www.fda.gov), and it will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, is available on the Internet and has been placed on public display and that copies are available upon request. FDA will publish in the **Federal Register** after each quarter a list of the denials announced in that quarter. When a notice of denial of approval is made publicly available, data and information in the PMA file will be available for public disclosure in accordance with § 814.9.

(2) A request for copies of the current PMA approvals and denials document and copies of summaries of safety and effectiveness shall be sent in writing to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

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Dated: January 22, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–2263 Filed 1–29–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 147

RIN 0790–AG54

Personnel Security Policies for Granting Access to Classified Information

AGENCY: Department of Defense.

ACTION: Interim final rule.

SUMMARY: This rule is published to streamline security practices throughout the government, uniform adjudicative guidelines, investigative standards and guidelines for temporary access are being established. This initiative will simplify security processing and allow the deserving public to obtain a security clearance in a faster, more efficient manner.

DATES: This rule is effective March 24, 1997. Comments must be received by March 31, 1998.

ADDRESSES: Forward comments to the Security Policy Board Staff, 1215 Jefferson Davis Highway, Suite 1101, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: Mr. T. Thompson, 703–602–9969.

SUPPLEMENTARY INFORMATION:

Executive Order 12866, Regulatory Planning and Review

It has been determined that this interim rule (32 CFR part 147) is not a significant regulatory action. The rule does not:

(1) Have an annual effect to the economy of $100 million or more or adversely affect in a material way the economy; a section of the economy; productivity; competition; jobs; the environment; public health or safety; or State, local, or tribal governments or communities;

(2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another Agency;

(3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof; or