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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise the premarket approval application (PMA) announcement procedure. FDA is proposing to discontinue the publication of PMA approvals and denials in the **Federal Register**. Instead, the agency is proposing to announce approvals and denials of PMA's on the Internet. Finally, FDA is proposing to make 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.

DATES: Written comments by September 25, 1997. FDA intends that any final rule based on this proposal become effective 30 days after its date of 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 preamble to the proposed rule prescribing the contents of a PMA and the criteria for approving, disapproving, or withdrawing approval of a PMA (45 FR 81769 at 81772, December 12, 1980), 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 notice of opportunity to petition for administrative review in the announcement 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 notice of opportunity for administrative review in the announcement 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).)

II. Contents of the Proposed Regulation

FDA is proposing to discontinue publication of individual PMA approvals and denials in the **Federal Register**. Instead, FDA is proposing to 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 Docket's 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 the proposed procedure would 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 would 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 would 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 only be sought by the applicant; in these cases, the 30-day period would 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 proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to asses 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 involves a minor procedural change that primarily affects FDA and has no direct effect on small companies, the agency certifies that this 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. Comments

Interested persons may, on or before September 25, 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 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, it is proposed that 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: Secs. 501, 502, 503, 510, 513–520, 701, 702, 703, 704, 705, 708, 721, 801 of the Federal Food, Drug, and Cosmetic Act (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 an 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: June 17, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–16792 Filed 6–26–97; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 36

RIN 1018–AE21

Regulations for Administrative and Visitor Facility Sites on National Wildlife Refuges in Alaska

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The Fish and Wildlife Service (Service) proposes this amendment to current regulations to provide the Service with the proper authority to enforce regulations concerning public safety, protection of government property, and applicable State of Alaska fish and wildlife regulations on administrative and visitor facility sites which commonly are located outside the approved boundaries of national wildlife refuges in Alaska.

DATES: For written comments to be considered, they must be received by August 26, 1997.

ADDRESSES: Comments should be sent to the Regional Director, Attention: Daryle R. Lons, U.S. Fish and Wildlife Service, 1011 E. Tudor Road, Anchorage, Alaska 99503.

FOR FURTHER INFORMATION CONTACT: Daryle R. Lons at the above address, telephone (907) 786–3354.

SUPPLEMENTARY INFORMATION:

Background

The National Wildlife Refuge System Administration Act of 1966 (16 U.S.C. 668dd–668ee) and section 1306 of the Alaska National Interest Lands Conservation Act of 1980 (ANILCA) (16 U.S.C. 3196) authorize the Secretary of the Interior to establish administrative sites and visitor facilities outside the boundaries of, and in the vicinity of, refuge units and to prescribe regulations governing use of such acquired lands.

The current regulations governing use on units of the National Wildlife Refuge System in Alaska, codified at 50 CFR part 36, were originally published in the **Federal Register** in 1981 (46 FR 31827, June 17, 1981 as corrected at 46 FR 40194, August 7, 1981), and were amended in 1986 (51 FR 44793, December 12, 1986). The existing regulations in part 36 only are applicable on federally-owned lands within the approved boundaries of Alaska National Wildlife Refuges. The Service currently has several administrative and visitor facility sites that are both inside and outside the approved boundaries of refuges, some of which are held in less than fee title. Examples of these sites include Alaska Maritime Refuge's Visitor Center and Headquarters Complex (fee title land) in Homer, Tetlin Refuge's two campgrounds (leased from the State of Alaska) near Northway, and Kenai Refuge's ''Sportsmen's Lodge'' access and parking area (leased from the State of Alaska and memorandum of understanding with the U.S. Forest Service) on the Kenai River at the Russian River confluence near Cooper Landing. Refuge officers currently do not have full authority to enforce applicable Federal and State regulations at these locations. The primary purpose of the revised regulations is to provide the Service with the proper regulatory authority to enforce regulations concerning public safety, protection of United States government property, and State of Alaska fish and resident wildlife statutes on these administrative