

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.

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

and visitor facility sites of national wildlife refuges in Alaska.

Request for Additional Comments

In accordance with Department policy, interested persons may submit written comments concerning this proposed rule by any of the following means: (1) Mailing to Daryle R. Lons, U.S. Fish and Wildlife Service, 1011 East Tudor Road, Anchorage, Alaska 99503-6199, (2) faxing to Daryle Lons at (907) 786-3657, or (3) electronically mailing to daryle_lons@mail.fws.gov. All substantive comments will be reviewed and considered before a final rule is published.

Paperwork Reduction Act

The Service has examined this regulation under the Paperwork Reduction Act of 1995 and found it to contain no information collection requirements.

Environmental Considerations

In accordance with 516 DM 2, Appendix 2, the Service has determined that this action is categorically excluded from the NEPA process as it contains "policies, directives, regulations and guidelines of an administrative, financial, legal, technical or procedural nature" that will have no potential for causing substantial environmental impact.

Economic Effects/Regulatory Flexibility Act Compliance

This rulemaking was not subject to review by the Office of Management and Budget under Executive Order 12866. The primary purpose of these 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 less than 10 administrative and visitor facility sites located both inside and outside the National Wildlife Refuges System in Alaska. 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. This proposed action is of an administrative nature only, and places no new economic or regulatory burden on the visiting public. Accordingly, under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*), this proposed rulemaking will not have a significant effect on a substantial number of small entities, which include businesses, organizations, or governmental jurisdictions.

Unfunded Mandates

The Service has determined and certifies pursuant to the Unfunded Mandates Act (2 U.S.C. 1502 *et seq.*), that this rulemaking will not impose a cost of \$100 million or more in any given year on local or State governments or private entities.

Civil Justice Reform

The Department has determined that these proposed regulations meet the applicable standards provided in sections 3(a) and 3(b)(2) of Executive Order 12988.

The primary author of this proposed regulation is Daryle R. Lons, Refuge Program Specialist, U.S. Fish and Wildlife Service, Alaska Region.

List of Subjects in 50 CFR Part 36

Alaska, Recreation and recreation areas, Reporting and recordkeeping requirements, Wildlife refuges.

Accordingly, the Service proposes to amend part 36 of Chapter I of Title 50 of the Code of Federal Regulations as follows:

PART 36—[AMENDED]

1. The authority citation for part 36 is revised to read as follows:

Authority: 5 U.S.C. 301, 16 U.S.C. 460(k) *et seq.*, 668dd *et seq.*, 742(a) *et seq.*, 3101 *et seq.*, and 44 U.S.C. 3501 *et seq.*

2. Section 36.1 is amended by revising paragraph (b), and adding paragraph (c) to read as follows:

§ 36.1 Applicability and scope.

* * * * *

(b) Except as provided in paragraph (c) of this section, the regulations contained in the following paragraphs of

this part are applicable only on federally-owned lands within the boundaries of any Alaska National Wildlife Refuge. For purposes of this part, "federally-owned lands" means land interests held or retained by the United States, but does not include those land interests:

(1) Tentatively approved, legislatively conveyed, or patented to the State of Alaska, or

(2) Interim conveyed or patented to a Native Corporation or person.

(c) The regulations found on 50 CFR, parts 25, 26, 27, and 28, and §§ 32.2(d) and 32.5(c), except as supplemented or modified by these regulations or amended by ANILCA, along with the regulations found in 50 CFR 36.35(d), also are applicable to administrative and visitor facility sites of the Fish and Wildlife Service in Alaska which may be held in fee or less than fee title and are either inside or outside the approved boundaries of any Alaska National Wildlife Refuge. Less than fee title lands include, but are not limited to, sites administered by a national wildlife refuge under the terms of a memorandum of understanding or lease agreement.

3. Section 36.2 is amended by removing paragraph designations (a) through (o), placing existing definitions in alphabetical order, and adding a new definition in alphabetical order as follows:

§ 36.2 Definitions.

* * * * *

Administrative and visitor facility sites means any facility or site administered by the U.S. Fish and Wildlife Service for public entry or other administrative purposes including, but not limited to, refuge staff offices, visitor centers, public access and parking sites, and campgrounds.

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4. Section 36.33(a) is amended by removing paragraph designations (1) through (11) and placing existing definitions in alphabetical order.

Dated: May 24, 1997.

Donald J. Barry,

Acting Assistant Secretary for Fish and Wildlife and Parks.

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