

are to be identified with the docket number found in brackets in the heading of this document. Received comments and requests 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 872

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 872 be amended as follows:

PART 872—DENTAL DEVICES

1. The authority citation for 21 CFR part 872 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 872.3600 is amended by revising paragraph (c) to read as follows:

§ 872.3600 Partially fabricated denture kit.

* * * * *

(c) *Date PMA or notice of completion of a PDP is required.* A PMA or a notice of completion of a PDP is required to be filed on or before (date 90 days after the effective date of a final rule based on this proposed rule), for any partially fabricated denture kit that was in commercial distribution before May 28, 1976, or that has on or before (date 90 days after the effective date of a final rule based on this proposed rule), been found to be substantially equivalent to a partially fabricated denture kit that was in commercial distribution before May 28, 1976. Any other partially fabricated denture kit shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: October 5, 1995.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 95-29083 Filed 11-28-95; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 32

RIN 1018-AD44

Addition of Great Bay National Wildlife Refuge to the List of Open Areas for Hunting in New Hampshire

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes to add Great Bay National Wildlife Refuge to the list of areas open for migratory game bird hunting and big game hunting in New Hampshire along with pertinent refuge-specific regulations for such activities. The Service has determined that such use will be compatible with the purposes for which the refuge was established. The Service has further determined that this action is in accordance with the provisions of all applicable laws, is consistent with principles of sound wildlife management, and is otherwise in the public interest by providing additional recreational opportunities of a renewable natural resource.

DATES: Comments may be submitted on or before January 29, 1996.

ADDRESSES: Assistant Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1849 C Street, NW, MS 670 ARLSQ, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Stephen R. Vehrs, at the address above; Telephone: 703-358-2029 X-5242.

SUPPLEMENTARY INFORMATION: National wildlife refuges are generally closed to hunting and sport fishing until opened by rulemaking. The Secretary of the Interior (Secretary) may open refuge areas to hunting and/or fishing upon a determination that such uses are compatible with the purpose(s) for which the refuge was established. The action must also be in accordance with provisions of all laws applicable to the areas, must be consistent with the principles of sound wildlife management, and must otherwise be in the public interest. This rulemaking proposes to open Great Bay National Wildlife Refuge to migratory game bird (waterfowl) hunting and big game (deer) hunting.

Request for Comments

Department of the Interior policy is, whenever practicable, to afford the public a meaningful opportunity to participate in the rulemaking process. A 60-day comment period is specified in order to facilitate public input.

Accordingly, interested persons may submit written comments concerning this proposed rule to the person listed above under the heading **ADDRESSES**. All substantive comments will be reviewed and considered.

Statutory Authority

The National Wildlife Refuge System Administration Act of 1966, as amended (NWRSA) (16 U.S.C. 668dd), and the Refuge Recreation Act of 1962 (RRA) (16 U.S.C. 460k) govern the administration

and public use of national wildlife refuges. Specifically, Section 4(d)(1)(A) of the NWRSA authorizes the Secretary to permit the use of any areas within the National Wildlife Refuge System (Refuge System) for any purpose, including but not limited to hunting, fishing, public recreation and accommodations, and access, when he determines that such uses are compatible with the purposes for which each refuge was established. The Director of the U.S. Fish and Wildlife Service (Director), administers the Refuge System on behalf of the Secretary. The RRA gives the Secretary additional authority to administer refuge areas within the Refuge System for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary purposes for which the refuges were established.

Opening Package

In preparation for this opening, the refuge unit has included in its "openings package" for Regional review and approval from the Washington Office the following documents: a management plan for recreational hunting; an environmental assessment; a Finding of No Significant Impact (FONSI); a Section 7 statement, pursuant to the Endangered Species Act, that this opening will not affect a listed species or its critical habitat; and refuge-specific regulations to administer the hunting program. From a review of the totality of these documents, The Service has determined that the opening of the Great Bay National Wildlife Refuge to hunting is compatible with the principles of sound wildlife management and will otherwise be in the public interest.

In accordance with the NWRSA and the RRA, the Service has also determined that this opening for hunting is compatible and consistent with the primary purposes for which the refuge was established. A brief description of the hunting program is as follows:

Great Bay National Wildlife Refuge

Great Bay National Wildlife Refuge was authorized in December, 1991, when an Act of Congress approved the transfer of 1,000 acres of land at Pease Air Force Base in Newington, New Hampshire to the Fish and Wildlife Service. The refuge was established August 11, 1992, with the signing of the transfer document. The refuge was established for the purposes (1) to encourage the natural diversity of plant, fish and wildlife species within the refuge, and to provide for their

conservation and management, (2) to protect species listed as endangered or threatened, or identified as candidates for listing pursuant to the Endangered Species Act of 1973, (3) to preserve and enhance the water quality of aquatic habitats within the refuge, and (4) to fulfill the international treaty obligations of the United States relating to fish and wildlife.

The refuge is located on the eastern shores of Great Bay. The refuge protects 922 acres of upland, 132 acres of wetlands, and 6.5 miles of Great Bay's shoreline. Wetland habitat types include 64 acres of open (fresh water) impoundments, 37 acres of forested wetlands, and 31 acres of salt marsh. The upland habitat includes 585 acres of hardwood forests interspersed with white pine, red pine, spruce, and fir, 200 acres of open (grasslands) area, and 137 acres of shrub dominate upland.

Waterfowl are commonly seen throughout the year. In 1994 spring waterfowl migration peaked around mid-April with over 300 birds observed. In summer the refuge supports breeding waterfowl. Typically, the fall waterfowl migration is larger than spring. In 1994, fall migration peaked around the end of October with over 900 birds observed. The refuge also supports wintering black ducks when open water is available. With wetland restoration and wetland habitat management, the refuge will be able to attract and support more breeding waterfowl.

Currently, the deer population is being monitored. High deer density and its effect on the habitat is the number one concern of the refuge. Habitat degradation can occur quickly and take many years to overcome. The refuge is constructing deer enclosures to monitor the condition of the habitat. An index of deer use during October and November has begun. A night spot-light count was conducted in 1993 and 1994 to monitor deer populations during these months. The index results show an increase in deer observed from 4.7 deer/night in 1993 to 11.5 deer/night in 1994. The University of New Hampshire is assisting the refuge in developing more detailed data. There is a need for deer harvesting due to the many years the Pease Air Force Base was off-limits to all but military personnel. The hunting of deer was, therefore, quite limited.

Opening the refuge to hunting has been found to be compatible in a separate compatibility determination. The hunting programs will be reviewed, as appropriate, to ensure that sensitive habitats are protected from disturbance. A Section 7 evaluation pursuant to the Endangered Species Act was conducted. The Service determined that the

proposed action will not affect any Federally listed or proposed for listing threatened or endangered species or their critical habitats. Pursuant to the National Environmental Policy Act (NEPA), an environmental assessment was made and a Finding of No Significant Impact (FONSI) was made regarding the hunting programs. Sufficient funds would be available within the refuge unit budget to operate the hunting programs as proposed.

Paperwork Reduction Act

The information collection requirements for Part 32 are found in 50 CFR Part 25 and have been approved by the Office of Management and Budget under Public Law 104-13 and assigned clearance number 1018-0014. The information is being collected to assist the Service in administering these programs in accordance with statutory authorities which require that recreational used be compatible with the primary purposes for which the areas were established. The information requested in the applicable form is required to obtain a benefit.

The public reporting burden for the application form is estimated to average six (6) minutes per response, including time for reviewing instructions, gathering and maintaining data, and completing the form. Direct comments on the burden estimate or any other aspect of this form to the Service Information Collection Officer, U.S. Fish and Wildlife Service, 1849 C Street NW., MS 224 ARLSQ, Washington, DC 20240; and the Office of Management and Budget, Paperwork Reduction Project (1018-0014), Washington, DC 20503.

Economic Effect

This rulemaking was not subject to Office of Management and Budget review under Executive Order 12866. In addition, a review under the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) has revealed that the rulemaking would not have a significant effect on a substantial number of small entities, which include businesses, organizations or governmental jurisdictions. While the proposed hunting programs could increase the number of hunting licenses purchased and boost sales of hunting gear, the impact would not be considered significant as other surrounding areas are, also, open to hunting and the addition of the refuge to those areas open for hunting would be only proportionally relevant to small entities. Therefore, this proposed rule would have minimal effect on such entities.

Federalism

This proposed rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient Federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Considerations

Pursuant to the requirements of section 102(2)(C) of the National Environmental Policy Act of 1969 (42 U.S.C. 4332(2)(C)), an environmental assessment has been prepared for this opening. Based upon the Environmental Assessment, the Service issued a Finding of No Significant Impact with respect to the opening. A Section 7 evaluation was prepared pursuant to the Endangered Species Act with a finding that the opening will not affect any identified threatened or endangered species or critical habitat. These documents are on file at the offices of the Service, and may be reviewed by making preliminary arrangements with the primary author.

Primary Author. Stephen R. Vehrs, Division of Refuges, U.S. Fish and Wildlife Service, Washington, DC, is the primary author of this rulemaking document.

List of Subjects in 50 CFR Part 32

Hunting, Fishing, Reporting and recordkeeping requirements, Wildlife, Wildlife refuges.

Accordingly, Part 32 of chapter I of Title 50 of the *Code of Federal Regulations* is proposed to be amended as set forth below:

PART 32—[AMENDED]

1. The authority citation for Part 32 continues to read as follows:

Authority: 5 U.S.C. 301; 16 U.S.C. 460k, 664, 668dd, and 715i.

§ 32.7 [Amended]

2. Section 32.7 List of refuge units open to hunting and/or fishing is amended to add the alphabetical listing of Great Bay National Wildlife Refuge under the State of New Hampshire.

3. Section 32.48 New Hampshire is added to read as follows:

§ 32.48 New Hampshire.

The following refuge units have been opened to hunting and/or fishing, and are listed in alphabetical order with applicable refuge-specific regulations.

Great Bay National Wildlife Refuge

A. Hunting of Migratory Game Birds.

Hunting of migratory game birds is permitted on designated areas of the refuge subject to the following conditions:

1. Waterfowl hunting will not require a permit. Hunting will be allowed only from the immediate shoreline of the Bay.

2. Only portable blinds are permitted. All decoys, blinds, and boats must be removed after each day's hunt.

3. Waterfowl hunters will access shorelines by boat only.

B. Upland Game Hunting. [Reserved]

C. Big Game Hunting. Hunting of deer is permitted on designated areas of the refuge subject to the following conditions:

1. Refuge permits are required for the deer hunt.

2. Big game hunters are required to wear in a conspicuous manner on the head, chest and back a minimum of 400 square inches of solid-colored blaze orange clothing or material.

D. Sport Fishing. [Reserved]

Dated: October 20, 1995.

George T. Frampton, Jr.,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 95-29106 Filed 11-28-95; 8:45 am]

BILLING CODE 4310-55-M

50 CFR Part 32**RIN 1018-AD43**

Addition of Ohio River Islands National Wildlife Refuge to the List of Open Areas for Sport Fishing in West Virginia

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: The U.S. Fish and Wildlife Service (Service) proposes to add Ohio River Islands National Wildlife Refuge to the list of areas open for sport fishing in West Virginia along with pertinent refuge-specific regulations for such activities. The Service has determined that such use will be compatible with the purposes for which the refuge was established. The Service has further determined that this action is in accordance with the provisions of all applicable laws, is consistent with principles of sound wildlife management, and is otherwise in the public interest by providing additional recreational opportunities of a renewable natural resource.

DATES: Comments may be submitted on or before January 29, 1996.

ADDRESSES: Assistant Director—Refuges and Wildlife, U.S. Fish and Wildlife Service, 1849 C Street NW., MS 670 ARLSQ, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT:

Stephen R. Vehrs, at the address above; Telephone: 703-358-2029 X-5242.

SUPPLEMENTARY INFORMATION: National wildlife refuges are generally closed to hunting and sport fishing until opened by rulemaking. The Secretary of the Interior (Secretary) may open refuge areas to hunting and/or fishing upon a determination that such uses are compatible with the purpose(s) for which the refuge was established. The action must also be in accordance with provisions of all laws applicable to the areas, must be consistent with the principles of sound wildlife management, and must otherwise be in the public interest. This rulemaking proposed to open Ohio River Islands National Wildlife Refuge to sport fishing

Request for Comments

Department of the Interior policy is, whenever practicable, to afford the public a meaningful opportunity to participate in the rulemaking process. A 60-day comment period is specified in order to facilitate public input. Accordingly, interested persons may submit written comments concerning this proposed rule to the person listed above under the heading **ADDRESSES**. All substantive comments will be reviewed and considered.

Statutory Authority

The National Wildlife Refuge System Administration Act of 1966, as amended (NWRSA) (16 U.S.C. 668dd), and the Refuge Recreation Act of 1962 (RRA) (16 U.S.C. 460k) govern the administration and public use of national wildlife refuges. Specifically, Section 4(d)(1)(A) of the NWRSA authorizes the Secretary to permit the use of any areas within the National Wildlife Refuge System (Refuge System) for any purpose, including but not limited to hunting, fishing, public recreation and accommodations, and access, when he determines that such uses are compatible with the purposes for which each refuge was established. The Director administers the Refuge System on behalf of the Secretary. The RRA gives the Secretary additional authority to administer refuge areas within the Refuge System for public recreation as an appropriate incidental or secondary use only to the extent that it is practicable and not inconsistent with the primary purposes for which the refuges were established.

Opening Package

In preparation for this opening, the refuge unit has included in its "openings package" for Regional review and approval from the Washington Office the following documents: a

management plan for recreational fishing; an environmental assessment; a Finding of No Significant Impact (FONSI); a Section 7 statement, pursuant to the Endangered Species Act, that this opening is not likely to adversely affect a listed species or its critical habitat; and refuge-specific regulations to administer the fishing program. From a review of the totality of these documents, the Service has determined that the opening of the Ohio River Islands National Wildlife Refuge to sport fishing is compatible with the principles of sound wildlife management and will otherwise be in the public interest.

In accordance with the NWRSA and the RRA, the Service has also determined that this opening for sport fishing is compatible and consistent with the primary purposes for which the refuge was established. A brief description of the fishing program is as follows:

Ohio River Islands National Wildlife Refuge

Established in 1990, the Ohio River Islands National Wildlife Refuge is located on the Ohio River from Shippingport, Pennsylvania to Manchester, Ohio. There are currently eighteen islands in the refuge totaling 1,020 acres. Through ongoing acquisition efforts, the refuge has the potential to include all, or portion of, 38 islands located along 362 river miles encompassing up to 3,500 acres of wildlife habitat.

The Ohio River islands and their back channels are recognized for high quality fish and wildlife, recreation, scientific, and natural heritage values. These areas provide some of the regions' highest quality riverine, wetland, and bottomland habitats, and are used by waterfowl, shorebirds, songbirds, warmwater fish, and freshwater mussels.

The Ohio River Islands National Wildlife Refuge was established under the authority of the Fish and Wildlife Act of 1956 (16 U.S.C. 742a-742j). The refuge's primary purposes is "* * * for the development, advancement, management, conservation, and protection of fish and wildlife resources", and "for the benefit of the United States Fish and Wildlife Service, in performing its activities and services." The objectives of the sport fishing program are (1) to provide for the wise use of renewable natural resources, (2) provide an opportunity for sport fishing and minimal interference from other anglers and freedom to participate in a natural setting, and (3) provide sport fishing opportunity when