environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1452 is amended by revising paragraphs (d)(2) and (d)(3) to read as follows:

§ 520.1452 Moxidectin gel.

* * * * *

(d) * * *

(2) *Indications for use.* Horses and ponies for treatment and control of large strongyles (*Strongylus vulgaris* (adults and L4/L5 arterial stages), *S. edentatus* (adult and tissue stages), *Triodontophorus brevicauda* (adults), *T. serratus* (adults)); small strongyles (*Cyathostomum* spp. (adults), *Cylicocyclus* spp. (adults), *Cylicostephanus* spp. (adults), *Gyalocephalus capitatus* (adults), undifferentiated lumenal larvae); encysted cyathostomes (late L3 and L4 mucosal cyathostome larvae); ascarids (*Parascaris equorum* (adults and L4 larval stages)); pinworms (*Oxyuris equi* (adults and L4 larval stages)); hairworms (*Trichostrongylus axei* (adults)); large-mouth stomach worms (*Habronema muscae* (adults)); and horse stomach bots (*Gasterophilus intestinalis* (2nd and 3rd instars) and *G. nasalis* (3rd instars)). One dose also suppresses strongyle egg production for 84 days.

(3) *Limitations.* Not for use in horses and ponies intended for food.

Dated: November 12, 1999.

Melanie R. Berson,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99–30571 Filed 11–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 805

[Docket No. 85N–0322]

Medical Devices; Revocation of Cardiac Pacemaker Registry

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revoke a regulation requiring a cardiac pacemaker registry. The registry, which was mandated by the Deficit Reduction Act of 1984, requires any physician and any provider of services who requests or receives Medicare payment for an implantation, removal, or replacement of permanent cardiac pacemaker devices and pacemaker leads to submit certain information to the registry. The information is used by FDA to track the performance of permanent cardiac pacemakers and pacemaker leads and by the Health Care Finance Administration (HCFA) to administer its Medicare payment program for these devices. This action is being taken to implement an act to Repeal An Unnecessary Medical Device Reporting Requirement passed by Congress in 1996 to remove the cardiac pacemaker registry to eliminate duplicative and unnecessary reporting.

DATES: This regulation is effective December 27, 1999.

FOR FURTHER INFORMATION CONTACT: Rosa M. Gilmore, Center for Devices and Radiological Health (HFZ–342), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2970.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 23, 1987 (52 FR 27756), FDA and HCFA jointly issued a final rule to establish a national cardiac pacemaker registry as mandated by the Deficit Reduction Act of 1984 (Public Law 98–369). The new law, which was enacted on July 18, 1984, amended title XVIII of the Social Security Act, by adding section 1862(h) (42 U.S.C. 1395y(h)) to the Social Security Act . FDA and HCFA jointly issued a proposed rule announcing the establishment of this registry in the **Federal Register** of May 6, 1986 (51 FR 16792).

The final rule for the cardiac pacemaker registry was codified in part 805 (21 CFR part 805). Briefly summarized, the scope of the regulation provides that FDA establish a nationwide registry for cardiac pacemakers and pacemaker leads. FDA used the information submitted to the registry to track the performance of permanent pacemakers and pacemaker leads and to perform studies and analysis regarding the use of the devices. The agency transmitted data to the HCFA to administer its Medicare program and to other Federal components to carry out statutory responsibilities.

On October 2, 1996, an act to Repeal An Unnecessary Medical Device Reporting Requirement (Public Law 104–224), which amended title XVIII of the Social Security Act (42 U.S.C. 1395), became law. The purpose of the new law was to remove section 1862(h) (42 U.S.C. 1395y(h)) of the Social Security Act to eliminate duplicative and unnecessary reporting.

When section 1862(h) was added to the Social Security Act, there was a need to identify and keep track of defective pacemakers. In particular, there was a need to identify circumstances in which a defective pacemaker was surgically implanted in a patient, and then surgically removed, with both procedures being paid for by Medicare. One of the main reasons for this early pacemaker registry was that there was no good way to track defective implantable medical devices, and no viable way for HCFA to recover costs in those circumstances where a defective product was used. Congress enacted an act to repeal section 1862(h) of the Social Security Act because the SMDA of 1990 (Public Law 101–629) added section 519(e) to the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(e)), which requires among other things that manufacturers track and collect data for certain devices, including permanently implanted pacemakers and pacemaker leads from the manufacturer through the distribution chain to the patient using the device.

Notice and comment rulemaking on the revocation of part 805 is unnecessary. The statutory authority for this rule has been revoked. Therefore, FDA concludes under 5 U.S.C. 553(b)(8) and 21 CFR 10.40(e)(1), that there is a good cause for revoking part 805 without notice and comment rulemaking.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

III. Analysis of Impact

FDA has examined the impacts of the final rule under Executive Order 12866, and the Regulatory Flexibility Act (5 U.S.C. 601–612) (as amended by subtitle D of the Small Business Reform Act of 1995 (Public Law 104–4)). Executive Order 12866 directs agencies to assess all costs and benefits of available 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. The final rule removes the medical device regulation requiring a national cardiac pacemaker registry from part 805. The agency certifies, under the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this final rule will not have a significant economic impact on a substantial number of small entities. In addition, this final rule will not impose expenditures of $100 million or more on either the private sector or State, local, and tribal governments in the aggregate and, therefore, a written statement under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

IV. Paperwork Reduction Act of 1995

FDA concludes that this final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required (Public Law 104–13).

List of Subjects in 21 CFR Part 805

Medical devices, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the authority of Public Law 104–224, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR Chapter 1 is amended as follows:

PART 805—CARDIAC PACEMAKER REGISTRY

1. Part 805 is removed.

Dated: November 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30570 Filed 11–23–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 903

[Docket No. FR–4420–N–05]

RIN 2577–AB89

Public Housing Agency Plans; Option To Extend First Submission Due Date for Certain Public Housing Agencies

AGENCY: Office of the Assistant Secretary for Public and Indian Housing, HUD.

ACTION: Notice of option to extend first submission date.

SUMMARY: This document provides notice to those public housing agencies (PHAs) that must submit their first Annual Plans in December 1999 or January 2000, that they have the option to submit their first plans between December 1, 1999 and January 31, 2000, or January 15, 2000 and February 29, 2000, respectively. HUD will soon be publishing additional information and direction to PHAs on their plan submissions. As a result, PHAs with December and January submission due dates may determine additional time is needed to prepare their first plans.

FOR FURTHER INFORMATION CONTACT: For further information contact the Office of Policy, Program and Legislative Initiatives, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 Seventh Street, SW, Room 4116, Washington, DC 20410; telephone (202) 708–0730 (this is not a toll-free number). Persons with hearing or speech impairments may access that number via TTY by calling the Federal Information Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: On October 21, 1999 (64 FR 56844), HUD published its final rule implementing section 511 of the Quality Housing and Work Responsibility Act of 1998. Section 511 introduces the public housing agency (PHA) plans—a 5-Year Plan and an Annual Plan. HUD will soon be publishing additional information and direction to PHAs about certain plan components, and the plan submission process. As a result, PHAs with December 1999 and January 2000 submission due dates may determine additional time is needed to prepare their first plans. HUD is therefore providing: (1) PHAs that previously were to submit their first 5-Year and Annual Plans on December 1, 1999, with the option to submit their first plans between December 1, 1999, and January 31, 2000; and (2) PHAs that previously were to submit their first 5-Year and Annual Plans on January 15, 2000, with the option to submit their first plans between January 15, 2000, and February 29, 2000.

Dated: November 19, 1999.

Harold Lucas,

Assistant Secretary for Public and Indian Housing.

[FR Doc. 99–30710 Filed 11–22–99; 10:53 am]

BILLING CODE 4210–33–P

DEPARTMENT OF TRANSPORTATION

33 CFR Part 100

[CGD07–99–057]

RIN 2115–AE46

Special Local Regulations: Puerto Rico International Cup, Fajardo, Puerto Rico

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: Temporary special local regulations are established for the Puerto Rico International Cup, in Fajardo, Puerto Rico. The event will be held from 1 p.m. to 2:30 p.m. on December 5, 1999, in Fajardo, Puerto Rico. These regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: These regulations become effective at 12 p.m. and terminate at 3:30 p.m. AST on December 5, 1999.

FOR FURTHER INFORMATION CONTACT: Mr. John Reyes at (787) 729–5381.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On August 31, 1999, the Coast Guard published a notice of proposed rulemaking concerning these regulations in the **Federal Register** (64 FR 47461). No comments were received during the comment period.

Background and Purpose

These regulations create a regulated area offshore Fajardo, Puerto Rico which prohibits entry to non-participating vessels during the race. The participating race boats will be competing at high speeds with numerous spectator craft in the area, thus creating an extra or unusual hazard on the navigable waterways. These regulations are required to provide for the safety of life on navigable waters during the Puerto Rico International Cup, in Fajardo, Puerto Rico.

In accordance with 5 U.S.C. 553, good cause exists for making this rule effective in less that 30 days after **Federal Register** publication. Delaying