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DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 292

[Docket No. RM09–23–000]

Revisions to Form, Procedures and Criteria for Certification of Qualifying Facility Status for a Small Power Production or Cogeneration Facility

AGENCY: Federal Energy Regulatory Commission.

ACTION: Correcting amendment.

SUMMARY: This document contains corrections to final regulations which were published in the **Federal Register** of Tuesday, March 30, 2010. The final rule document adopted revisions to FERC Form 556 and to Commission procedures and criteria for the certification of qualifying facility status for a small power production or cogeneration facility.

DATES: August 16, 2011.

FOR FURTHER INFORMATION CONTACT: S.L. Higginbottom (Legal Information), Office of the General Counsel, Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, *Telephone:* 202–502–8561, *E-mail: samuel.higginbottom@ferc.gov.*

SUPPLEMENTARY INFORMATION: The final regulations amended 18 CFR 292.205 and affect the Commission's criteria and procedures for the certification of qualifying facility status for small power production or cogeneration facilities.

As published, the final regulations contained errors; they incorrectly removed paragraphs from 18 CFR 292.205(d). These paragraphs contain critical criteria for new cogeneration facilities.

List of Subjects in 18 CFR Part 292

Electric power, Electric power plants, Electric utilities.

Accordingly, 18 CFR part 292 is corrected by making the following correcting amendment:

Subchapter K—Regulations Under The Public Utility Regulatory Policies Act of 1978

PART 292—REGULATIONS UNDER SECTION 201 AND 210 OF THE PUBLIC UTILITY REGULATORY POLICIES ACT OF 1978 WITH REGARD TO SMALL POWER PRODUCTION AND COGENERATION

■ 1. The authority citation for part 292 continues to read as follows:

Authority: 16 U.S.C. 791a–825r, 2601–2645; 31 U.S.C. 9701; 42 U.S.C. 7101–7352.

■ 2. Section 292.205 is amended by adding paragraphs (d)(1) through (5) to read as follows:

§ 292.205 Criteria for qualifying cogeneration facilities.

* * * * *

(d) * * *

(1) The thermal energy output of the cogeneration facility is used in a productive and beneficial manner; and

(2) The electrical, thermal, chemical and mechanical output of the cogeneration facility is used fundamentally for industrial, commercial, residential or institutional purposes and is not intended fundamentality for sale to an electric utility, taking into account technological, efficiency, economic, and variable thermal energy requirements, as well as state laws applicable to sales of electric energy from a qualifying facility to its host facility.

(3) Fundamental use test. For the purpose of satisfying paragraph (d)(2) of this section, the electrical, thermal, chemical and mechanical output of the cogeneration facility will be considered used fundamentally for industrial, commercial, or institutional purposes, and not intended fundamentally for sale to an electric utility if at least 50 percent of the aggregate of such output, on an annual basis, is used for industrial, commercial, residential or institutional purposes. In addition, applicants for facilities that do not meet this safe harbor standard may present evidence to the Commission that the facilities should nevertheless be certified given state laws applicable to sales of electric energy or unique technological, efficiency, economic, and variable thermal energy requirements.

(4) For purposes of paragraphs (d)(1) and (2) of this section, a new cogeneration facility of 5 MW or smaller will be presumed to satisfy the requirements of those paragraphs.

(5) For purposes of paragraph (d)(1) of this section, where a thermal host existed prior to the development of a new cogeneration facility whose thermal output will supplant the thermal source previously in use by the thermal host, the thermal output of such new cogeneration facility will be presumed to satisfy the requirements of paragraph (d)(1).

Dated: August 9, 2011.

Kimberly D. Bose,

Secretary.

[FR Doc. 2011–20751 Filed 8–15–11; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 870 and 884

[Docket No. FDA–2010–N–0412]

Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following three class III preamendments devices: Ventricular bypass (assist) device; pacemaker repair or replacement material; and female condom. The Agency has summarized its findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. This action implements certain statutory requirements.

DATES: This rule is effective August 23, 2011.

FOR FURTHER INFORMATION CONTACT: Michael Ryan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 1615, Silver Spring, MD 20993–0002, 301–796–6283.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295), the Safe Medical Devices Act of 1990 (SMDA) (Pub. L. 101–629), the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115), the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107–250), and the Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85), among other amendments, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the FD&C Act, devices that were in commercial distribution before the enactment of the 1976 amendments, May 28, 1976 (generally referred to as preamendments devices), are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976 (generally referred to as postamendments devices) are automatically classified by section 513(f) of the FD&C Act into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval unless, and until, the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and 21 CFR part 807.

A preamendments device that has been classified into class III may be marketed by means of premarket notification procedures (510(k) process) without submission of a PMA until FDA issues a final regulation under section 515(b) of the FD&C Act (21 U.S.C. 360e(b)) requiring premarket approval. Section 515(b)(1) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the FD&C Act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) is not required to have an approved investigational device exemption (IDE) (see part 812 (21 CFR part 812)) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the FD&C Act provides that a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The regulation; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the FD&C Act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the FD&C Act. Section 515(b)(3) of the FD&C Act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval or publish a document terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the FD&C Act, unless the reason for termination is that the device is a banned device under section 516 of the FD&C Act (21 U.S.C. 360f).

When a rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the FD&C Act (21 U.S.C. 351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the FD&C Act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, commercial distribution of the device must cease since the device would be deemed adulterated under section 501(f).

The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the latter of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the FD&C Act, and subject to seizure and condemnation under section 304 of the FD&C Act (21 U.S.C. 334), if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the FD&C Act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the FD&C Act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III device that is the subject of this regulation.

The FD&C Act does not permit an extension of the 90-day period after issuance of a final rule within which an application or notice is required to be filed. The House Report on the 1976 amendments states that ''* * * [t]he thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application of

premarket approval'' (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

The SMDA added section 515(i) to the FD&C Act requiring FDA to review the classification of preamendments class III devices for which no final rule requiring the submission of PMAs has been issued, and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, the SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. The SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the FD&C Act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Proceeding directly to rulemaking under section 515(b) of the FD&C Act is consistent with Congress' objective in enacting section 515(i), i.e., that preamendments class III devices for which PMAs have not been previously required either be reclassified to class I or class II or be subject to the requirements of premarket approval.

In the **Federal Register** of May 6, 1994 (59 FR 23731) (the May 6, 1994, notice), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy document set forth FDA's plans for implementing the provisions of section 515(i) of the FD&C Act for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups as referenced in the May 6, 1994, notice.

In the **Federal Register** of August 25, 2010 (75 FR 52294) (the August 25, 2010, proposed rule), FDA published a proposed rule to require the filing under section 515(b) of the FD&C Act of a PMA or notice of completion of a PDP for four premendments class III devices: Ventricular (bypass) assist device; pacemaker repair or replacement material; female condom; and transilluminator for breast evaluation. In accordance with section 515(b)(2)(A) of the FD&C Act, FDA included in the preamble of the proposal the Agency's tentative findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to meet the premarket approval requirements of the FD&C Act, and the benefits to the public from use of the device. The August 25, 2010, proposed rule also provided an opportunity for interested persons to submit comments on the proposed rule and the Agency's findings. Under section 515(b)(2)(B) of the FD&C Act, FDA provided an opportunity for interested persons to request a change in the classification of the device based on new information relevant to its classification. Any petition requesting a change in classification of the devices was required to be submitted by September 9, 2010. The comment period closed November 23, 2010.

FDA received no comments on the proposed rule. FDA received one petition requesting a change in the classification of the transilluminator for breast evaluation. FDA has yet to resolve the request; therefore, the transilluminator for breast evaluation is not subject to this final rule.

II. Findings With Respect to Risks and Benefits

Under section 515(b)(3) of the FD&C Act, FDA is adopting its findings as published in the August 25, 2010, proposed rule with the exception of the findings related to the transilluminator for breast evaluation. As required by section 515(b) of the FD&C Act, FDA published its findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP and (2) the benefits to the public from the use of the devices.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with information submitted in response to the 515(i) Order, (74 FR 16214, April 9, 2009), and any additional information that FDA has encountered. Additional information regarding the risks as well as classification associated with these device types can be found in the following proposed and final rules published in the **Federal Register** on these dates: Cardiovascular Devices—part 870 (21 CFR part 870) (44 FR 13284, March 9, 1979 and 45 FR 7904, February 5, 1980, 52 FR 17732 at 17736, May 11, 1987); and Obstetrical and Gynecological Devices—part 884 (21 CFR part 884) (64 FR 31164, June 10, 1999, and 65 FR 31454, May 18, 2000).

III. The Final Rule

Under section 515(b)(3) of the FD&C Act, FDA is adopting its findings as published in the preamble to the proposed rule with the exception of the findings related to the transilluminator for breast evaluation. FDA is issuing this final rule to require premarket approval of these generic types of devices for class III preamendments devices by revising parts 870 and 884.

Under the final rule, a PMA or a notice of completion of a PDP is required to be filed on or before 90 days after the date of publication of the final rule in the **Federal Register,** for any of these class III preamendments devices that were in commercial distribution before May 28, 1976, or that has been found by FDA to be substantially equivalent to such a device on or before 90 days after the date of publication of the final rule in the **Federal Register**. An approved PMA or a declared completed PDP is required to be in effect for any such devices on or before 180 days after FDA files the application. Any other class III preamendments device subject to this rule that was not in commercial distribution before May 28, 1976, is required to have an approved PMA or a declared completed PDP in effect before it may be marketed.

If a PMA or a notice of completion of a PDP for any of these class III preamendments devices is not filed on or before the 90th day past the effective date of this regulation, that device will be deemed adulterated under section 501(f)(1)(A) of the FD&C Act, and commercial distribution of the device will be required to cease immediately. The device may, however, be distributed for investigational use, if the requirements of the IDE regulations (part 812) are met.

IV. 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.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess 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 final rule is not a significant regulatory action under Executive Order 12866.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because there have been no premarket submissions for these devices in the past 5 years and all of the affected devices have fallen into disuse, FDA has

concluded that there is little or no interest in marketing these devices in the future. Therefore, the Agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities.

Section 202(a) of the Unfunded Mandates Reform Act of 1995 requires that Agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing ''any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year.'' The current threshold after adjustment for inflation is $136 million, using the most current (2010) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

FDA has concluded that this final rule will not have a significant impact. We base this determination on an analysis of registration and listing and other data for the affected devices. Two of the devices affected by this final rule, the female condom and ventricular bypass device, have never appeared in FDA's electronic registration and listing database. These devices were identified as preamendment devices, but since their classification, the Agency has no record of them ever being marketed. In addition, these devices represent older technologies that have since been replaced by newer technologies currently being marketed under a PMA.

The final affected device, pacemaker repair and replacement material, is a material that can be used in multiple devices that was last listed in 2001, and the Agency is aware of no evidence that the device has been marketed since 1991. In addition, on the increasingly rare occasions when a pacemaker is repaired today, the repair is done with materials specific to the approved device. This information is summarized in table 1 of this document as follows.

TABLE 1—SUMMARY OF ELECTRONIC REGISTRATION AND LISTING INFORMATION

Device name	Product code	510(k) or PMA?	Last listed	Last marketed	Replaced by approved technology?
Female Condom	OBY	No	Never Listed	1930s	Yes.
Ventricular Bypass Device	OKR	No	Never Listed	No Record	Yes.
Pacemaker Repair and Replacement	KFJ	No	2001	1991	Yes.

Based on our review of electronic product registration and listing and other data, FDA concludes that there is currently little or no interest in marketing the affected devices and that the final rule will not have a significant economic impact.

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that 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. Accordingly, the Agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VII. Paperwork Reduction Act of 1995

This final rule refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subpart B, have been approved under OMB control number 0910–0231; and the collections of information under 21 CFR part 801 have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Parts 870 and 884

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 870 and 884 are amended as follows:

PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Section 870.3545 is amended by revising paragraph (c) to read as follows:

§ 870.3545 Ventricular bypass (assist) device.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any ventricular bypass (assist) device that was in commercial distribution before May 28, 1976. Any other ventricular bypass (assist) device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

■ 3. Section 870.3710 is amended by revising paragraph (c) to read as follows:

§ 870.3710 Pacemaker repair or replacement material.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any pacemaker repair or replacement material device that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any pacemaker repair or replacement material device that was in commercial distribution before May 28, 1976. Any other pacemaker repair or replacement material device shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

■ 4. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 5. Section 884.5330 is amended by revising paragraph (c) to read as follows:

§ 884.5330 Female condom.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before November 21, 2011, for any female condom that was in commercial distribution before May 28, 1976, or that has, on or before November 21, 2011, been found to be substantially equivalent to any female condom that was in commercial distribution before May 28, 1976. Any other female condom shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: August 10, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20664 Filed 8–15–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2011–0708]

RIN 1625–AA11

Regulated Navigation Area; Portsmouth Naval Shipyard, Portsmouth, NH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a regulated navigation area on the Piscataqua River near Portsmouth, NH. This temporary final rule places speed restrictions on all vessels transiting the navigable waters on the Piscataqua River, Portsmouth, NH near the Portsmouth Naval Shipyard between Henderson Point Light on Seavey Island and Badgers Island Buoy 14. This rule is necessary to provide for the safety of life on the navigable waters during ongoing ship construction.

DATES: This rule is effective from August 16, 2011 until 5 p.m. on September 5, 2011. This rule will be enforced with actual notice from 7 a.m. on August 5, 2011 until 5 p.m. on September 5, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2011–0708 and are available online by going to *http://www.regulations.gov,* inserting USCG–2011–0708 in the ''Keyword'' box, and then clicking ''Search.'' They are also available for inspection or copying at the Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail Lieutenant Junior Grade Terence Leahy, Waterways Management Division at Coast Guard Sector Northern New England, telephone 207–767–0398, e-mail *Terence.O.Leahy@uscg.mil* or Lieutenant Junior Grade Isaac Slavitt, Waterways Management Division at Coast Guard First District, telephone 617–223–8385. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because the Coast Guard was not notified of the need for this rule until 13 July 2011, and the Portsmouth Naval Facility will begin diving operations in this area within a short timeframe making publication of a NPRM and Final Rule impractical. This regulated navigation area is necessary to provide for the safety of the divers and others working in the area as wake from passing vessels could cause the ship to move erratically and unexpectedly, injuring the divers and their support crews. Not providing for the safety of the divers and others in the area is contrary to the public interest of creating a safe work environment.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register** as immediate action is necessary to provide for the safety of divers and workers on the vessel. In addition to the reasons stated within this preamble, a delay in the effective date of this rule is contrary to the public's interest in ensuring the ship construction project continues as scheduled.

Basis and Purpose

Under the Ports and Waterways Safety Act, the Coast Guard has the authority to establish RNAs in defined water areas that are determined to have hazardous conditions and in which vessel traffic can be regulated in the interest of safety. See 33 U.S.C. 1231 and Department of Homeland Security Delegation No. 0170.1.

As part of ongoing ship construction projects at the Portsmouth Naval Shipyard, divers will be working on the hull of a vessel for approximately four weeks beginning on August 5, 2011. Unexpected and uncontrolled movement of the vessel due to wake while divers are in the water creates a significant risk of serious injury or death. In order to ensure the safety of vessel workers such as divers during the period of ship construction work, the Coast Guard is creating a regulated navigation area to limit the speed, and thus wake, of all vessels operating in the vicinity of the shipyard.

Discussion of Rule

This action places speed restrictions on all vessels transiting the navigable waters on the Piscataqua River, Portsmouth, NH near the Portsmouth Naval Shipyard between Henderson Point Light on Seavey Island and Badgers Island Buoy 14 when necessary for the safety of navigation during periods of ship construction work. All vessels operating in this area shall proceed with caution; operate at no more than 5 knots and in a manner so as to produce no wake. Diving operations and other vessel construction may occur at any time, day or night.

The Captain of the Port Sector Northern New England will cause notice of enforcement or suspension of enforcement of this regulated navigation area to be made by all appropriate means in order to affect the widest distribution among the affected segments of the public. Such means of notification will include, but is not limited to, Broadcast Notice to Mariners