burden on the manufacturers of MDDSs. The burden of compliance with the general controls provisions applicable to the manufacturers of all class I devices is attributable to statutory requirements that already apply but in the past have not been enforced for MDDSs. Because continued exercise of enforcement discretion may not be a viable long-term regulatory alternative, this final rule reduces the ultimate regulatory burden for manufacturers of MDDSs.

Considering the cost of submitting a PMA plus the relevant user fees, the reduction could be $1,000,000 per device.

The Regulatory Flexibility Act requires Agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of the affected devices from class III to class I will relieve manufacturers of the cost of complying with the premarket approval requirements of section 515 of the FD&C Act (21 U.S.C. 360e), the Agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.

VII. 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 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.

VIII. Paperwork Reduction Act of 1995

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.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:


2. Section 880.6310 is added to subpart G to read as follows:

§ 880.6310 Medical device data system.

(a) Identification. (1) A medical device data system (MDDS) is a device that is intended to provide one or more of the following uses, without controlling or altering the functions or parameters of any connected medical devices:

(i) The electronic transfer of medical device data;

(ii) The electronic storage of medical device data;

(iii) The electronic conversion of medical device data from one format to another format in accordance with a preset specification; or

(iv) The electronic display of medical device data.

(2) An MDDS may include software, electronic or electrical hardware such as a physical communications medium (including wireless hardware), modems, interfaces, and a communications protocol. This identification does not include devices intended to be used in connection with active patient monitoring.

(b) Classification. Class I (general controls), The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9.

Dated: February 9, 2011.

Nancy K. Stade,

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

[FR Doc. 2011–3231 Filed 2–14–11; 8:45 am]

BILLING CODE 4160–61–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends Pension Benefit Guaranty Corporation’s regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in March 2011. Interest assumptions are also published on PBGC’s Web site (http://www.pbgc.gov).

DATES: Effective March 1, 2011.
Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

<table>
<thead>
<tr>
<th>Rate set</th>
<th>For plans with a valuation date</th>
<th>Immediate annuity rate (percent)</th>
<th>Deferred annuities (percent)</th>
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<tbody>
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<td>On or after Before</td>
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<tr>
<td>209</td>
<td>3–1–11 4–1–11</td>
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<td>2.50</td>
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</tbody>
</table>

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

<table>
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<tr>
<th>Rate set</th>
<th>For plans with a valuation date</th>
<th>Immediate annuity rate (percent)</th>
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</table>
DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2010–1093]

RIN 1625–AA08

Special Local Regulation; Mavericks Surf Competition, Half Moon Bay, CA

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary special local regulation on certain navigable waters of Half Moon Bay in support of the Mavericks Surf Competition. This special local regulation is necessary to ensure the safety of participants and spectators during the event. Entry into this zone is prohibited unless authorized by the Captain of the Port San Francisco, CA.

DATES: This rule is effective from February 15, 2011 through February 28, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2010–1093 and are available online by going to http://www.regulations.gov, inserting USCG–2010–1093 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 Lieutenant Junior Grade Liezl Nicholas at (415) 399–7436, or e-mail D11–PF–MarineEvents@uscg.mil. 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 immediate action is needed to provide for the safety of life and property on navigable waters. Because of the dangers posed by the surf conditions during the Mavericks Surf Competition, the special local regulation is necessary to provide for the safety of event participants, spectators, spectator craft, and other vessels transiting the event area. For the safety concerns noted, it is in the public interest to have these regulations in effect during the event.

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. Any delay in the effective date of this rule would expose mariners to the dangers posed by the surf conditions during the Mavericks Surf Competition.

Basis and Purpose

The Mavericks Surf Competition is a one day “Big Wave” surfing competition consisting of the top 24 big wave surfers and only occurs when 15–20 foot waves are sustained for over 24 hours and are combined with mild easterly winds of no more than 5–10 knots. Because weather conditions are integral to the occurrence of the Maverick Surf Competition, the exact date of the event cannot be determined in advance. The rock and reef ridges that make up the sea floor of the Pillar Point area combined with just the right weather conditions create the large waves that Mavericks is known for. Due to the treacherous terrain and un-navigable areas surrounding Pillar Point, the Coast Guard is establishing a special local regulation within a 1,000 yard radius of Pillar Point that restricts navigation near the surf competition area and neighboring treacherous terrain and identifies the safest area for spectator viewing on the water.

Discussion of Rule

The Coast Guard is establishing a special local regulation within a 1,000 yard radius of Pillar Point in Half Moon Bay. The Mavericks Surf Competition will occur in the vicinity of Pillar Point in the navigable waters of Half Moon Bay, and the spectator viewing area will be located inside the following coordinates: 37°29.265′N 122°30.165′W, 37°29.248′N 122°29.978′W, and 37°29.406′N 122°30.081′W (NAD 83). Competitors, participating agencies (Coast Guard, San Mateo Police Marine Patrol, Pillar Point Harbor Patrol, San Mateo Fire Marine Patrol) and the public (to include but not restricted to: Commercial sightseeing vessels, photographer platforms and recreational boaters) will be given 48 hours notice prior to the start of the one day competition. This action is necessary to ensure the safety of participants and spectators during the event. During the enforcement period, unauthorized persons (persons not classified as spectators, participants or participating agencies) or vessels are prohibited from transiting through, anchoring, blocking, or loitering in the regulated area without permission of the Captain of the Port (COTP) or their designated representative.

The effect of the temporary special local regulation will be to regulate navigation in the vicinity of Pillar Point while the Mavericks Surf Competition is taking place. Except for persons or vessels authorized by the Coast Guard Patrol Commander (persons classified as spectators, participants or participating agencies), no person or vessel may transit within the bounds of the regulated area. These regulations are needed to keep spectators and vessels a safe distance away from the event participants and the un-navigable waters surrounding Pillar Point and to ensure the safety of participants, spectators, and transiting vessels.

The Coast Guard will enforce the temporary special local regulation from 8 a.m. to 3 p.m. on a date to be determined. Notification of the enforcement of the special local regulation will be provided to the public via broadcast notice to mariners, as well as through advertising on local media.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and