

Under these conditions, FDA believes that it is appropriate to categorically exclude the establishment of a special control from the requirement to prepare an EA or EIS.

B. HDE

FDA is amending § 25.34 to include approval of an HDE as a category of action that does not individually or cumulatively have a significant effect on the human environment and for which neither an EA nor EIS is required. Because humanitarian use devices are limited by definition to use for treating or diagnosing diseases or conditions affecting fewer than 4,000 individuals in the United States per year, any environmental impact associated with use of a humanitarian use device is very limited. FDA approves few HDEs, further limiting any potential environmental impact. FDA's experience in reviewing HDEs has shown that no HDE reviewed thus far has had a significant environmental impact.

V. Environmental Impact

The agency has determined that under 21 CFR 24.30(h) 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.

VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs 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 the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule provides for an exclusion from the requirement to prepare an EA or EIS and, as such, relieves a burden, the agency certifies that this final rule will not have a significant economic impact on 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 finalizing "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 \$115 million, using the most current (2003) 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.

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 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.

VIII. Paperwork Reduction Act of 1995

This final rule contains no collection 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 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of the Food and Drug Administration, 21 CFR part 25 is amended as follows:

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 1. The authority citation for 21 CFR part 25 continues to read as follows:

Authority: 21 U.S.C. 321-393; 42 U.S.C. 262, 263b-264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500-1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531-533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123-124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356-360.

■ 2. Section 25.34 is amended by revising paragraph (b) and adding paragraph (i) to read as follows:

§ 25.34 Devices and electronic products.

* * * * *

(b) Classification or reclassification of a device under part 860 of this chapter, including the establishment of special controls, if the action will not result in increases in the existing levels of use of the device or changes in the intended use of the device or its substitutes.

* * * * *

(i) Approval of humanitarian device exemption under subpart H of part 814 of this chapter.

Dated: October 14, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05-22563 Filed 11-14-05; 8:45 am]

BILLING CODE 4160-01-S

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in December 2005. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

DATES: Effective December 1, 2005.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, Attorney, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202-326-4024. (TTY/TDD users may call the Federal relay service toll-free at 1-800-877-8339 and ask to be connected to 202-326-4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of

the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) A set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to Part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to Part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to Part 4022).

This amendment (1) Adds to Appendix B to Part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during December 2005, (2) adds to Appendix B to Part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during December 2005, and (3) adds to Appendix C to Part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during December 2005.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 4.00 percent for the first 20 years following

the valuation date and 4.75 percent thereafter. These interest assumptions represent an increase (from those in effect for November 2005) of 0.30 percent for the first 20 years following the valuation date and are otherwise unchanged.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 2.75 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent an increase (from those in effect for November 2005) of 0.25 percent for the period during which a benefit is in pay status and are otherwise unchanged.

For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during December 2005, the PBGC finds that good cause exists for making the assumptions set forth in

this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a "significant regulatory action" under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

■ In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 146, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | | |
|----------|---------------------------------|-------------|----------------------------------|------------------------------|----------------|----------------|----------------|----------------|--|
| | On or after | Before | | i ₁ | i ₂ | i ₃ | n ₁ | n ₂ | |
| * 146 | * 12-1-05 | * 1-1-06 | * 2.75 | * 4.00 | * 4.00 | * 4.00 | * 7 | * 8 | |

■ 3. In appendix C to part 4022, Rate Set 146, as set forth below, is added to the table.

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

* * * * *

| Rate set | For plans with a valuation date | | Immediate annuity rate (percent) | Deferred annuities (percent) | | | | | |
|----------|---------------------------------|-------------|----------------------------------|------------------------------|----------------|----------------|----------------|----------------|--|
| | On or after | Before | | i ₁ | i ₂ | i ₃ | n ₁ | n ₂ | |
| * 146 | * 12-1-05 | * 1-1-06 | * 2.75 | * 4.00 | * 4.00 | * 4.00 | * 7 | * 8 | |

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

■ 4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.
 ■ 5. In appendix B to part 4044, a new entry for December 2005, as set forth below, is added to the table.

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

| For valuation dates occurring in the month— | The values of i_t are: | | | | | |
|---|--------------------------|---------|-------|---------|-------|---------|
| | i_t | for t = | i_t | for t = | i_t | for t = |
| December 2005 | .0400 | 1–20 | .0475 | >20 | N/A | N/A |

Issued in Washington, DC, on this 9th day of November 2005.

James J. Armbruster,
Acting Director, Legislative and Regulatory Department, Pension Benefit Guaranty Corporation.
 [FR Doc. 05–22604 Filed 11–14–05; 8:45 am]
 BILLING CODE 7708–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–05–126]

RIN 1625–AA08

Special Local Regulations for Marine Events; Approaches to Annapolis Harbor, Spa Creek and Severn River, Annapolis, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations at 33 CFR 100.511 during the Eastport Yacht Club Lights Parade, a marine event to be held December 10, 2005, on the waters of Spa Creek and the Severn River at Annapolis, Maryland. These special local regulations are necessary to control vessel traffic due to the confined nature of the waterway and expected vessel congestion during the event. The effect will be to restrict general navigation in the regulated area for the safety of event participants, spectators and vessels transiting the event area.

DATES: 33 CFR 100.511 will be enforced from 5:30 p.m. to 8:30 p.m. on December 10, 2005.

FOR FURTHER INFORMATION CONTACT:

Ronald Houck, Marine Events Coordinator, Commander, Coast Guard Sector Baltimore, 2401 Hawkins Point Road, Baltimore, MD 21226–1971, and (410) 576–2674.

SUPPLEMENTARY INFORMATION: The Eastport Yacht Club will sponsor a lighted boat parade on the waters of Spa Creek and the Severn River at Annapolis, Maryland. The event will consist of approximately 50 boats traveling at slow speed along two separate parade routes in Annapolis Harbor. The participating boats will range in length from 10 to 60 feet, and each will be decorated with holiday lights. In order to ensure the safety of participants, spectators and transiting vessels, 33 CFR 100.511 will be enforced for the duration of the event. Under provisions of 33 CFR 100.511, vessels may not enter the regulated area without permission from the Coast Guard Patrol Commander. Spectator vessels may anchor outside the regulated area but may not block a navigable channel. Because these restrictions will be in effect for a limited period, they should not result in a significant disruption of maritime traffic.

In addition to this notice, the maritime community will be provided extensive advance notification via the Local Notice to Mariners, marine information broadcasts, and area newspapers, so mariners can adjust their plans accordingly.

Dated: November 2, 2005.

Larry L. Hereth,
Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. 05–22574 Filed 11–14–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD05–05–123]

RIN 1625–AA87

Security Zone; Cape Fear River, Eagle Island, North Carolina State Port Authority Terminal, Wilmington, NC

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary security zone at the North Carolina State Port Authority (NCSPA), Wilmington to include the Cape Fear River and Eagle Island. Entry into or movement within the security zone will be prohibited without authorization from the Captain of the Port (COTP), Wilmington, NC. This action is necessary to safeguard the vessels and the facility from sabotage, subversive acts, or other threats.

DATES: This rule is effective from October 1, 2005, until December 31, 2005.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD05–05–123 and are available for inspection or copying at the Marine Safety Unit 721 Medical Center Drive, Suite 100, Wilmington, North Carolina 28401 between 7:30 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LTJG Diego Benavides, Branch Chief, Port Safety and Security (910) 772–2200 or toll free (877) 229–0770.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this rule. The Coast Guard is promulgating this security zone regulation to protect NCSPA Wilmington and the