

reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined because of the risks of false positives and false negatives that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device and, therefore, this type of device is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the norovirus serological reagents they intend to market.

#### V. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of 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, Executive Order 13563, the Regulatory Flexibility Act (Pub. L. 96–354) (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 proposed rule is not a significant regulatory action as defined by 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 this rule is deregulatory and imposes no new burdens, the Agency proposes to certify 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 proposed 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. Section 4(a) of the Executive Order requires Agencies to “construe \* \* \* a Federal statute to preempt State law only where the statute contains an express preemption provision or there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.” Federal law includes an express preemption provision that preempts certain state requirements “different or in addition to” certain federal requirements applicable to devices. 21 U.S.C. 360k; See *Medtronic v. Lohr*, 518 U.S. 470 (1996); *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). The special controls established by this rulemaking create “requirements” to address each identified risk to health presented by these specific medical devices under 21 U.S.C. 360k, even though product sponsors may have flexibility in how they meet those requirements. Cf. *Papike v. Tambrands, Inc.*, 107 F.3d 737, 740–42 (9th Cir. 1997).

#### VIII. Paperwork Reduction Act of 1995

This final rule establishes as special controls a guidance document that refers to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance document entitled “Class II Special Controls Guidance Document: Norovirus Serological Reagents.” The notice contains an analysis of the paperwork burden for the guidance.

#### IX. References

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Petition from R-Biopharm AG, c/o Lehnus and Associates, dated February 15, 2011.

#### List of Subjects in 21 CFR Part 866

Biologics, Laboratories, 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 866 is amended as follows:

#### PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 1. The authority citation for 21 CFR part 866 continues to read as follows:

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

■ 2. Section 866.3395 is added to subpart D to read as follows:

#### § 866.3395 Norovirus serological reagents.

(a) *Identification.* Norovirus serological reagents are devices that consist of antigens and antisera used in serological tests to detect the presence of norovirus antigens in fecal samples. These devices aid in the diagnosis of norovirus infection in the setting of an individual patient with symptoms of acute gastroenteritis when the individual patient is epidemiologically linked to other patients with symptoms of acute gastroenteritis and/or aid in the identification of norovirus as the etiology of an outbreak of acute gastroenteritis in the setting of epidemiologically linked patients with symptoms of acute gastroenteritis.

(b) *Classification.* Class II (special controls). The special control is FDA’s guidance document entitled “Class II Special Controls Guidance Document: Norovirus Serological Reagents.” See § 866.1(e) for the availability of this guidance document.

Dated: March 5, 2012.

**Nancy K. Stade,**

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

[FR Doc. 2012–5675 Filed 3–8–12; 8:45 am]

**BILLING CODE 4160–01–P**

#### PENSION BENEFIT GUARANTY CORPORATION

#### 29 CFR Part 4044

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

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Correcting amendments.

**SUMMARY:** The Pension Benefit Guaranty Corporation published a final rule document in the **Federal Register** on September 15, 2011 (at 76 FR 56973), amending its regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under those regulations. This document corrects an inadvertent error in that final rule relating to the prescribed interest assumption under the allocation regulation, applicable to plans with valuation dates during the fourth quarter of 2011.

**DATES:** Effective March 9, 2012.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion (*Klion.Catherine@PBGC.gov*), Manager, Regulatory and Policy Division, 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 Pension Benefit Guaranty Corporation published a final rule document in the **Federal Register** of September 15, 2011 (at 76 FR 56973), amending its regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under those regulations. The rule inadvertently misstated the prescribed interest assumptions under the allocation regulation, applicable to plans with valuation dates during the fourth quarter of 2011. The errors appeared both in the preamble and in the amendatory instructions.

In the preamble, the first full paragraph in the second column on p. 56974 should have read as follows:

The fourth quarter 2011 interest assumptions under the allocation regulation will be 4.09 percent for the first 20 years following the valuation date and 4.30 percent thereafter. In comparison with the interest assumptions in effect for the third quarter of 2011, these interest assumptions represent no

change in the select period (the period during which the select rate (the initial rate) applies), a decrease of 0.13 percent in the select rate, and a decrease of 0.04 percent in the ultimate rate (the final rate).

**List of Subjects in 29 CFR Part 4044**

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR part 4044 is corrected by making the following correcting amendment:

**PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS**

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

**Authority:** 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

■ 2. In appendix B to part 4044, the entry for October–December 2011 is corrected to read as follows:

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

\* \* \* \* \*

For valuation dates occurring in the months—	The values of $i_t$ are:					
	$i_t$	for $t =$	$i_t$	for $t =$	$i_t$	for $t =$
October–December 2011 .....	0.0409	1–20	0.0430	>20	N/A	N/A
* * *	*	*	*	*	*	*

Issued in Washington, DC, on this 6th day of March 2012.

**Laricke Blanchard,**  
*Deputy Director for Policy, Pension Benefit Guaranty Corporation.*

[FR Doc. 2012-5786 Filed 3-8-12; 8:45 am]

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**PENSION BENEFIT GUARANTY CORPORATION**

**29 CFR Part 4044**

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

**AGENCY:** Pension Benefit Guaranty Corporation.

**ACTION:** Correcting amendments.

**SUMMARY:** The Pension Benefit Guaranty Corporation published a final rule document in the **Federal Register** on June 15, 2011 (at 76 FR 34847), amending its regulations on Benefits Payable in Terminated Single-Employer

Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under those regulations. This document corrects an inadvertent error in that final rule relating to the prescribed interest assumption under the allocation regulation, applicable to plans with valuation dates during the third quarter of 2011.

**DATES:** Effective March 9, 2012.

**FOR FURTHER INFORMATION CONTACT:** Catherine B. Klion (*Klion.Catherine@PBGC.gov*), Manager, Regulatory and Policy Division, 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 Pension Benefit Guaranty Corporation published a final rule document in the **Federal Register** of June 15, 2011 (at 76 FR 34847), amending its regulations on Benefits Payable in Terminated Single-

Employer Plans and Allocation of Assets in Single-Employer Plans to prescribe interest assumptions under those regulations. The rule inadvertently misstated the prescribed interest assumptions under the allocation regulation, applicable to plans with valuation dates during the third quarter of 2011. The errors appeared both in the preamble and in the amendatory instructions.

In the preamble, the third full paragraph in the second column on p. 34847 should have read as follows:

The third quarter 2011 interest assumptions under the allocation regulation will be 4.22 percent for the first 20 years following the valuation date and 4.34 percent thereafter. In comparison with the interest assumptions in effect for the second quarter of 2011, these interest assumptions represent no change in the select period (the period during which the select rate (the initial rate) applies), an increase of 0.26 percent in the select rate, and an increase of 0.02 percent in the ultimate rate (the final rate).

**List of Subjects in 29 CFR Part 4044**

Employee benefit plans, Pension insurance, Pensions.