

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

21 CFR Parts 807, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, and 892

[Docket No. 2006N-0335]

Medical Devices; Reprocessed Single-Use Devices; Requirement for Submission of Validation Data; Withdrawal

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published a direct final rule that appeared in the *Federal Register* of September 25, 2006 (71 FR 55729), that would have amended certain classification regulations for reprocessed single-use devices (SUDs) whose exemption from premarket notification (510(k)) requirements have been terminated and other reprocessed SUDs already subject to premarket notification for which validation data, as specified under the Medical Device User Fee and Modernization Act of 2002, are necessary in a 510(k). FDA stated in the direct final rule that, if it received a significant adverse comment by December 11, 2006, FDA would publish a notice of withdrawal. FDA received two comments and considers at least one of these comments a significant adverse comment and, therefore, is withdrawing the direct final rule. Accordingly, the agency will consider the comments received under our usual procedures for notice and comment in connection with the notice of proposed rulemaking that was published in the *Federal Register* of September 25, 2006 (71 FR 55748) as a companion to the direct final rule.

DATES: The direct final rule published at 71 FR 55729 on September 25, 2006, is withdrawn as of January 12, 2007.

FOR FURTHER INFORMATION CONTACT: Heather S. Rosecrans, Center for Devices and Radiological Health (HFZ-404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-4040.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on September 25, 2006 (71 FR 55729), is withdrawn.

Dated: January 9, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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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 February 2007. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

DATES: Effective February 1, 2007.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion, 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 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 February 2007, (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 February 2007, 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 February 2007.

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 5.13 percent for the first 20 years following the valuation date and 4.80 percent thereafter. These interest assumptions represent an increase (from those in effect for January 2007) of 0.25 percent for the first 20 years following the valuation date and 0.25 percent for all years thereafter.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.00 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 January 2007) of 0.25 percent in the immediate annuity rate 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 current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during February 2007, 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).