

than 24 hours (one day), additional or alternative labeling may be necessary. FDA would like comments regarding labeling, such as the following:

- How often to apply the product,
- The effect of bathing or showering before the duration of effect period ends, and
- Whether any other special labeling should apply to products with a duration of effect greater than 24 hours.

FDA also requests comments on whether there should be any limit on the enhanced duration claim and whether there are any potential safety issues if a product with enhanced duration of action is reapplied more frequently than directed (e.g., an antiperspirant labeled as providing 48 hours of sweat protection applied every 24 hours).

IV. Analysis of Impacts

The economic impact of the FM was discussed in the final rule (68 FR 34273 at 34289). This partial stay of the labeling claims for enhanced duration in § 350.50(b)(3) and (b)(5) does not change the economic impact on industry described in the final rule.

FDA has examined the impacts of this final rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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). Under the Regulatory Flexibility Act, if a rule has a significant economic impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million (adjusted annually for inflation). The current inflation adjusted statutory threshold is about \$110 million.

FDA concludes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order and in these two statutes. The final rule is not a significant regulatory action as defined by the Executive order and so is not

subject to review under the Executive order. FDA has determined that the final rule does not have a significant economic impact on a substantial number of small entities. The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this final rule, because this final rule is not expected to result in any 1-year expenditure that would exceed \$100 million adjusted for inflation.

The purpose of this final rule is to stay the effective date of one part of the antiperspirant FM: The limitation of the enhanced duration claim to 24 hours (§ 350.50(b)(3) and (b)(5)). The partial stay will allow manufacturers who have supporting data to include greater than 24 hour duration claims in the labeling of OTC antiperspirant drug products while FDA evaluates data to support such claims using FDA's effectiveness test. FDA has learned that one manufacturer has approximately 40 stockkeeping units (SKUs) and another manufacturer has several SKUs with labels indicating effectiveness for more than 24 hours. These manufacturers will not have to revise the existing "enhanced duration" portion of their labeling when the FM becomes effective on December 9, 2004. Accordingly, FDA certifies that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

V. Paperwork Reduction

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.

VI. Environmental Impact

FDA has determined under 21 CFR 25.31(a) 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.

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, FDA 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. Request for Comments

Interested persons may submit written or electronic comments regarding this rule to the Division of Dockets Management (see **ADDRESSES**). Three copies of all written comments are to be submitted. Individuals submitting written comments or anyone submitting electronic comments may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IX. References

The following references are on display in the Division of Dockets Management (see **ADDRESSES**) under Docket No. 1978N–0064 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Comment No. PRC1.
2. Comment No. PRC2.
3. Comment No. SUP4.
4. Comment No. C54.

X. Authority

This final rule (partial stay) is issued under sections 201, 501, 502, 503, 505, 510, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, and 371) and under authority delegated to the Commissioner of Food and Drugs.

Dated: October 6, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–23106 Filed 10–14–04; 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 November 2004. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

DATES: November 1, 2004.

FOR FURTHER INFORMATION CONTACT:

Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, 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).

Accordingly, 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 November 2004, (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 November 2004, 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 November 2004.

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 3.80 percent for the first 20 years following the valuation date and 5.00 percent thereafter. These interest assumptions represent a decrease (from those in effect for October 2004) of 0.20 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 a decrease (from those in effect for October 2004) 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 November 2004, 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 133, as set forth below, is added to the table. (The introductory text of the table is omitted.)

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
*	*	*	*	*	*	*	*	
133	11-1-04	12-1-04	2.75	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 133, as set forth below, is added to the table. (The introductory text of the table is omitted.)

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
*	*	*	*	*	*	*	*	*
133	11-1-04	12-1-04	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, as set forth below, is added to the table. (The introductory text of the table is omitted.)

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 =
*	*	*	*	*	*	*
November 20040380	1-20	.0500	>20	N/A	N/A

Issued in Washington, DC, on this 12th day of October 2004.
Joseph H. Grant,
Deputy Executive Director and Chief Operating Officer, Pension Benefit Guaranty Corporation.
 [FR Doc. 04-23180 Filed 10-14-04; 8:45 am]
BILLING CODE 7708-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 64

[CC Docket No. 96-146; RM-8783; ENF-95-20; FCC 04-162]

Policies and Rules Governing Interstate Pay-Per-Call and Other Information Services, and Toll-free Number Usage; Truth-in-Billing and Billing Format

AGENCY: Federal Communications Commission.

ACTION: Final rules.

SUMMARY: In this document, the Commission closes CC Docket 96-146, a rulemaking initiated in 1996 to implement portions of the Telecommunications Act of 1996 (1996 Act) governing pay-per-call and related information services. This docket was opened specifically for the purpose of implementing section 228 as amended by the 1996 Act. In 1996, the Commission released an *Order and Notice of Proposed Rulemaking* that adopted new rules, incorporating much of the statute verbatim, and completed

implementation of the new provision of section 228. In the years since the rules took effect, the shape of the pay-per-call industry, technology in general, and regulatory perspectives have changed considerably. For reasons of administrative efficiency, the Commission now closes that docket. Furthermore, in this document, the Commission denies a related application for review, dismisses a petition to initiate a rulemaking, and corrects a word error in the existing rules.

DATES: Effective July 16, 2004.

ADDRESSES: Federal Communications Commission, 445 12th Street, SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Ruth Yodaiken, of the Consumer & Government Affairs Bureau at (202) 418-2512 (voice), or e-mail ruth.yodaiken@fcc.gov.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Memorandum Opinion and Order (MO&O), *Policies and Rules Governing Interstate Pay-Per-Call and Other Information Services Pursuant to the Telecommunications Act of 1996, Policies and Rules Implementing the Telephone Disclosure and Dispute Resolution Act, Florida Public Service Commission Petition to Initiate Rulemaking to Adopt Additional Safeguards; Application for Review of Advisory Ruling Regarding Directly Dialed Calls to International Information Services*, CC Docket No.

96-146, RM 8783, ENF-95-20; FCC 04-162, adopted July 1, 2004, and released July 16, 2004. This MO&O document does not contain new or modified information collection requirements subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104-13. In addition, therefore, it does not contain any new or modified "information collection burden for small business concerns with fewer than 25 employees," pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, see 44 U.S.C. 3506(c)(4). On July 16, 2004, the Commission also released a Notice of Proposed Rulemaking (NPRM), *Policies and Rules Governing Interstate Pay-Per-Call and Other Information Services Pursuant to the Telecommunications Act of 1996; Policies and Rules Governing Interstate Pay-Per-Call and Other Information Services, and Toll-free Number Usage; Truth-in-Billing and Billing Format*, CC Docket Nos. 96-146 and 98-170, CG Docket No. 04-244; FCC 04-162, that contains proposed information requirements. The full text of this document is available on the Commission's website Electronic Comment Filing System and for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 12th Street, SW., Washington, DC 20554. To request materials in accessible formats for people with disabilities (Braille, large print, electronic files, audio format), send an e-mail to fcc504@fcc.gov, or call the Consumer & Governmental Affairs