

proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under 5 U.S.C. 553 or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form. Although there is no public comment period, public comments on this regulation are welcome on a continuing basis. Comments should be submitted to Sheila Quartermann, Regulatory Policy Division, Bureau of Industry and Security, Department of Commerce, P.O. Box 273, Washington, DC 20044.

5. This rule has been determined to be major for purposes of the Congressional Review Act (5 U.S.C. 801 *et seq.*). However, pursuant to the Congressional Review Act (5 U.S.C. 808(2)), the Bureau of Industry and Security has determined that the delay in the effective date generally required by the Congressional Review Act is waived for good cause. In particular, the Bureau has determined that a delay is impracticable because a delay in effective date would allow for the shipment of goods during that delay that would be antithetical to the objective of this rule.

#### List of Subjects in 15 CFR Part 736

Exports, Foreign trade.

■ Accordingly, part 736 of the Export Administration Regulations (15 CFR parts 730–799) is amended as follows:

#### PART 736—[AMENDED]

■ 1. The authority citation for part 736 is revised to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp. p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338 of May 11, 2004; Notice of August 7, 2003, 68 FR 47833, 3 CFR, 2003 Comp., p. 328; Notice of October 29, 2003, 68 FR 62209, 3 CFR, 2003 Comp., p. 347.

■ 2. Supplement No. 1 to part 736 is amended by adding General Order No. 2 to read as follows:

#### Supplement No. 1 to Part 736—General Orders

\* \* \* \* \*

General Order No. 2 of May 14, 2004; sections 5(a)(1) and 5(a)(2)(A) of the Syria Accountability and Lebanese Sovereignty Act of 2003 (Public Law 108–175, codified as a note to 22 U.S.C. 2151) (the SAA), require (1) a prohibition on the export to Syria of all items on the Commerce Control List (in 15

CFR part 774)(CCL) and (2) a prohibition on the export to Syria of products of the United States, other than food and medicine. The President has also exercised national security waiver authority pursuant to Section 5(b) of the SAA for certain transactions. This Order is issued consistent with Executive Order 13338 of May 11, 2004, which implements the SAA.

(a) *License requirements.* Effective May 14, 2004, a license is required for export or reexport to Syria of all items subject to the EAR, except food and medicine classified as EAR99 (medicine is defined in part 772 of the EAR). A license is required for the “deemed export” and “deemed reexport,” as described in § 734.2(b) of the EAR, of any technology or source code on the Commerce Control List (CCL) to a Syrian foreign national. “Deemed exports” and “deemed reexports” involving technology or source code subject to the EAR but not listed on the CCL do not require a license to Syrian foreign nationals.

(b) *Revocation of Authority to Export under Existing Licenses.* Effective May 14, 2004, the authority to export or reexport to Syria under existing licenses is hereby revoked (see savings clause in paragraph (e) of this General Order). License conditions requiring written U.S. Government authorization for the reexport, transfer, or resale of items already exported or reexported remain in effect, and requests for BIS authorization to reexport, transfer, or sell such items will require interagency approval.

(c) *License Exceptions.* Effective May 14, 2004, no License Exceptions to the license requirements set forth in paragraph (a) of this General Order are available for exports or reexports to Syria, except the following:

(1) TMP for items for use by the news media as set forth in § 740.9(a)(2)(viii) of the EAR.

(2) GOV for items for personal or official use by personnel and agencies of the U.S. Government as set forth in § 740.11(b)(2)(i) and (ii) of the EAR.

(3) TSU for operation technology and software, sales technology and software updates pursuant to the terms of § 740.13(a), (b), or (c) of the EAR.

(4) BAG for exports of items by individuals leaving the United States as personal baggage pursuant to the terms of § 740.14 (a) through (d) only of the EAR, and

(5) AVS for the temporary sojourn of civil aircraft reexported to Syria pursuant to the terms of § 740.15(a)(4) of the EAR.

(d) *Licensing policy.* All license applications for export or reexport to Syria are subject to a general policy of denial. License applications for “deemed exports” and “deemed reexports” of technology and source code will be reviewed on a case-by-case basis. BIS may consider, on a case-by-case basis, license applications for exports and reexports of items necessary to carry out the President’s constitutional authority to conduct U.S. foreign affairs and as Commander-in-Chief, including those exports and reexports of items necessary for the performance of official functions by the United States Government personnel abroad. BIS may also consider the following license applications on a case-by-case basis: items in

support of activities, diplomatic or otherwise, of the United States Government (to the extent that regulation of such exportation or reexportation would not fall within the President’s constitutional authority to conduct the nation’s foreign affairs); medicine (on the CCL) and medical devices (both as defined in part 772 of the EAR); parts and components intended to ensure the safety of civil aviation and the safe operation of commercial passenger aircraft; aircraft chartered by the Syrian Government for the transport of Syrian Government officials on official Syrian Government business; telecommunications equipment and associated computers, software and technology; and items in support of United Nations operations in Syria. The total dollar value of each approved license for aircraft parts for flight safety normally will be limited to no more than \$2 million over the 24-month standard license term, except in the case of complete overhauls. In addition, consistent with part 734 of the EAR, the following are not subject to this General Order: informational materials in the form of books and other media; publicly available software and technology; and technology exported in the form of a patent application or an amendment, modification, or supplement thereto or a division thereof (see 15 CFR 734.3(b)(1)(v), (b)(2) and (b)(3)).

(e) *Savings Clause.* Items that are on dock for loading, on lighter, laden aboard an exporting carrier or en route aboard a carrier to a port of export on May 14, 2004, shall be subject to the licensing rules applicable to such items as of May 13, 2004. Any such items not actually exported or reexported before midnight May 28, 2004, may be exported or reexported only if authorized pursuant to this General Order.

\* \* \* \* \*

Dated: May 11, 2004.

**Peter Lichtenbaum,**  
*Assistant Secretary for Export Administration.*

[FR Doc. 04–11059 Filed 5–12–04; 10:14 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 600

[Docket No. 2003N–0528]

### Revision of the Requirements for Spore-Forming Microorganisms; Confirmation of Effective Date

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Direct final rule; confirmation of effective date.

**SUMMARY:** The Food and Drug Administration (FDA) is confirming the effective date of June 1, 2004, for the direct final rule that appeared in the

**Federal Register** of December 30, 2003 (68 FR 75116). The direct final rule amends the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. This document confirms the effective date of the direct final rule.

**DATES:** Effective date confirmed: June 1, 2004.

**FOR FURTHER INFORMATION CONTACT:**

Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of December 30, 2003 (68 FR 75116), FDA issued a direct final rule amending the biologics regulations by providing options to the existing requirement for separate, dedicated facilities and equipment for work with spore-forming microorganisms. The regulations were amended due to advances in facility, system, and equipment design and in sterilization technologies that allow work with spore-forming microorganisms to be performed in multiproduct manufacturing areas.

FDA solicited comments concerning the direct final rule for a 75-day period ending March 15, 2004. FDA stated that the effective date of the direct final rule would be on June 1, 2004, unless any significant adverse comment was submitted to FDA during the comment period. FDA received only one comment (from private industry) on the direct final rule. The comment requested FDA to revise § 600.11(e)(4) (21 CFR 600.11(e)(4)), and asked whether this rulemaking affects the interpretation of § 600.11(e)(4). That comment is beyond the scope of this rulemaking, which is not intended to affect the requirements for live vaccine processing set forth in § 600.11(e)(4). FDA has determined that the received comment is not a significant adverse comment.

Authority: Therefore, under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act and under authority delegated to the Commissioner of Food and Drugs, the amendments issued thereby become effective on June 1, 2004.

Dated: May 7, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-11027 Filed 5-13-04; 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 June 2004. Interest assumptions are also published on the PBGC's Web site (<http://www.pbgc.gov>).

**DATES:** *Effective Date:* June 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 June 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 June 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 June 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 4.30 percent for the first 20 years following the valuation date and 5.00 percent thereafter. These interest assumptions represent an increase (from those in effect for May 2004) of 0.40 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 3.50 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 May 2004) of 0.50 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 June 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).