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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 600

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[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.

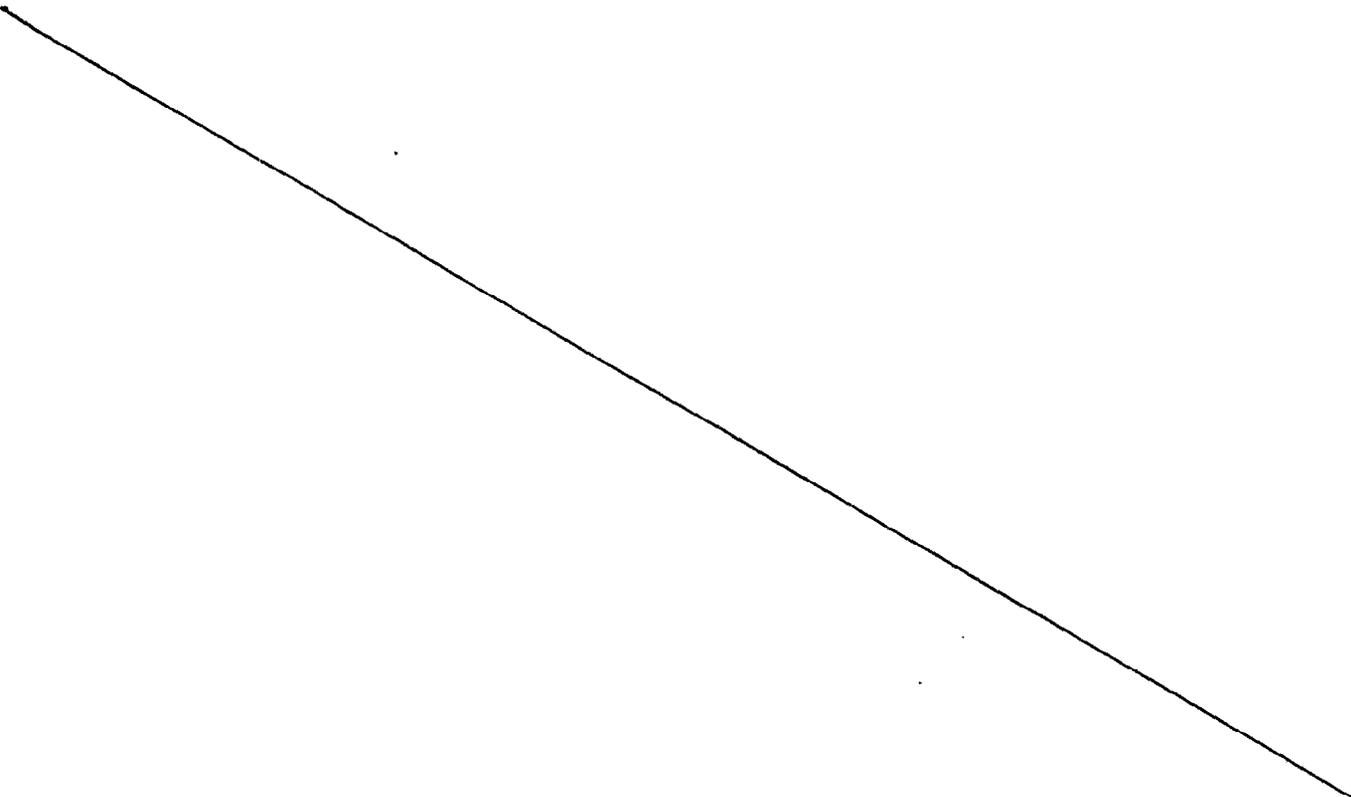
FOR FURTHER INFORMATION CONTACT: Valerie A. Butler, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

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: 5/7/04
May 7, 2004.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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