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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2003N-0528]

**Draft Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms; Availability**

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

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms" dated February 2005. The draft document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The draft guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

**DATES:** Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication the Federal Register*], to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug

Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the CBER Voice Information System at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

**FOR FURTHER INFORMATION CONTACT:** Valerie A. Butler, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Manufacturing Biological Drug Substances, Intermediates, or Products Using Spore-Forming Microorganisms” dated February 2005. The draft document is intended to provide guidance to manufacturers using spore-forming microorganisms in the production of certain biological products. The draft guidance document provides recommendations to industry in response to changes made to the requirements for spore-forming microorganisms to allow greater flexibility in manufacturing.

In the **Federal Register** of December 30, 2003, FDA published the direct final rule entitled “Revision of the Requirements for Spore-Forming Microorganisms” (68 FR 75116) and the accompanying proposed rule entitled

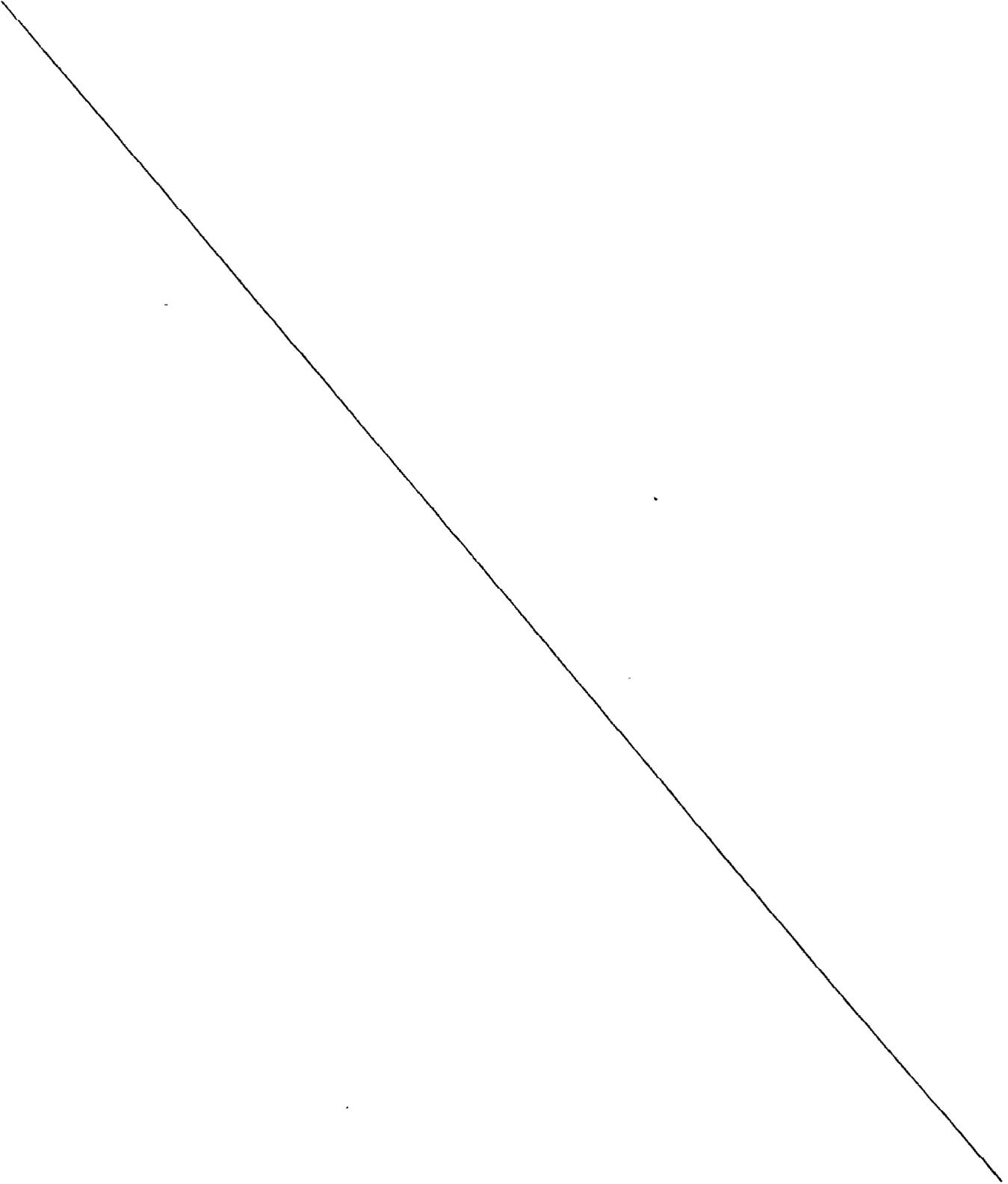
“Revision of the Requirements for Spore-Forming Microorganisms; Companion to Direct Final Rule” (68 FR 75179) to modify the regulatory requirements for the manufacturing of biological products with spore-formers to allow greater manufacturing flexibility. The modifications were intended to provide alternatives to the then-existing requirements for separate, dedicated facilities and equipment for work with spore-forming microorganisms. In the **Federal Register** of May 14, 2004 (69 FR 26768), FDA published the “Revision of the Requirements for Spore-Forming Microorganisms; Confirmation of Effective Date” confirming the effective date of June 1, 2004, for the direct final rule.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statutes and regulations.

## **II. Comments**

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are

available for public examination in the Division of Dockets Management  
between 9 a.m. and 4 p.m., Monday through Friday.



**III. Electronic Access**

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 2/16/05  
February 16, 2005.

*Joelle*

  
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Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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