

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-1999-D-0128] (formerly Docket No. 1999D-2013)

**Guidance for Industry: Cooperative Manufacturing Arrangements for  
Licensed Biologics; 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 document entitled "Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics," dated November 2008. The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under the U.S. Public Health Service Act (PHS Act). The guidance describes the licensing strategies for meeting the increased need for flexible manufacturing arrangements. The guidance announced in this notice finalizes the draft guidance of the same title.

**DATES:** Submit written or electronic comments on agency guidances at any time.

**ADDRESSES:** Submit written requests for single copies of the 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, suite 200N, Rockville, MD 20852-1448, or the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm.

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NAD

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Display Date

10-3-08

Publication Date

10-4-08

Certifier

A. Corbin

2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the 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.regulations.gov*.

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

David Cummings, Center for Drug Evaluation and Research (HFD–354), Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 21, rm. 3525, Silver Spring, MD 20993, 301–796–2400.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a document entitled “Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics” dated November 2008. The guidance document provides information concerning the various cooperative manufacturing arrangements used in the production of biological products subject to licensure under section 351 of the PHS Act (42 U.S.C. 262). The guidance describes FDA’s current thinking on licensing strategies for meeting the increased need for planning flexible manufacturing arrangements. Because cooperative manufacturing arrangements can take a considerable amount of time to develop, the guidance may also be

useful for planning purposes in the early phases of product development. Several types of manufacturing arrangements discussed in the guidance include short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements. The guidance supersedes “FDA’s Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics” published in the **Federal Register** of November 25, 1992 (57 FR 55544).

In the **Federal Register** of August 3, 1999 (64 FR 42136), FDA announced the availability of the draft guidance of the same title dated August 1999. FDA received several comments on the draft guidance; those comments were considered as the guidance was finalized. In response to public comments, we clarified the document and reformatted it into plain language. In the **Federal Register** of July 23, 2007 (72 FR 40157), FDA published a 60-day notice requesting public comment on the information collections in the draft guidance of the same title dated July 2007, which revised the draft guidance dated August 1999. The guidance announced in this notice finalizes the draft guidance dated July 2007.

The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’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 requirements of the applicable statutes and regulations.

## **II. Paperwork Reduction Act of 1995**

This guidance contains information collection provisions that are subject to review by the Office of Management (OMB) under the Paperwork Reduction

Act of 1995 (44 U.S.C. 3501–3520). The collections of information in this guidance were approved under OMB control number 0910–0629.

### **III. Comments**

Interested persons may, at any time, submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this 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 the brackets in the heading of this document. A copy of the 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *<http://www.regulations.gov>*.

**IV. Electronic Access**

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/cber/guidelines.htm* or *http://www.regulations.gov*.

Dated: 10/24/08  
November 24, 2008.

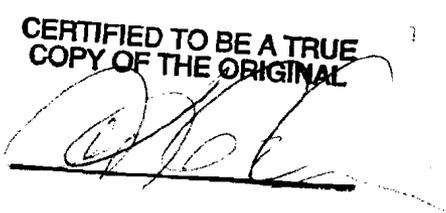


Jeffrey Shuren,  
Associate Commissioner for Policy and Planning.

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