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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2013]

Draft "Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics"; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics." This draft guidance, once finalized, will supersede the guidance entitled "FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics," previously made available in the **Federal Register**, that describes innovative arrangements among applicants who wish to cooperate in the manufacture of a licensed biological product. This draft guidance is now being revised to reflect recent changes in the biologics regulations and to provide for additional flexibility in cooperative manufacturing arrangements. The draft guidance is intended to assist manufacturers in the development and production of both conventional and biotechnology-derived biological products, and to increase flexibility in the licensing options for biological products without diminishing the protection of public health.

DATES: Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 days after date of publication in the Federal Register*), to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft "Guidance for Industry: Cooperative Manufacturing Arrangements for Licensed Biologics" 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 request. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800, or by fax by calling the FAX Information System at 1-888-CBER-FAX or 301-827-3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

Submit written comments on the document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Gloria J. Hicks, 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: Cooperative Manufacturing Arrangements for Licensed Biologics." Once finalized, this document will supersede "FDA's Policy Statement Concerning Cooperative Manufacturing Arrangements for Licensed Biologics," published in the **Federal Register** of November 25, 1992 (57 FR 55544). This revised guidance document is intended to advise current and potential manufacturers of biological and biotechnology products subject to licensure under section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) of available cooperative manufacturing arrangements. These arrangements include short supply, divided manufacturing, shared manufacturing, and contract manufacturing.

CBER recognizes that because development of important new biological products is both expensive and time consuming, increasing flexibility in manufacturing arrangements is desirable. In the **Federal Register** of May 14, 1996 (61 FR 24227), FDA published a final rule amending the biologics regulations at 21 CFR 601.2 to eliminate the establishment license application

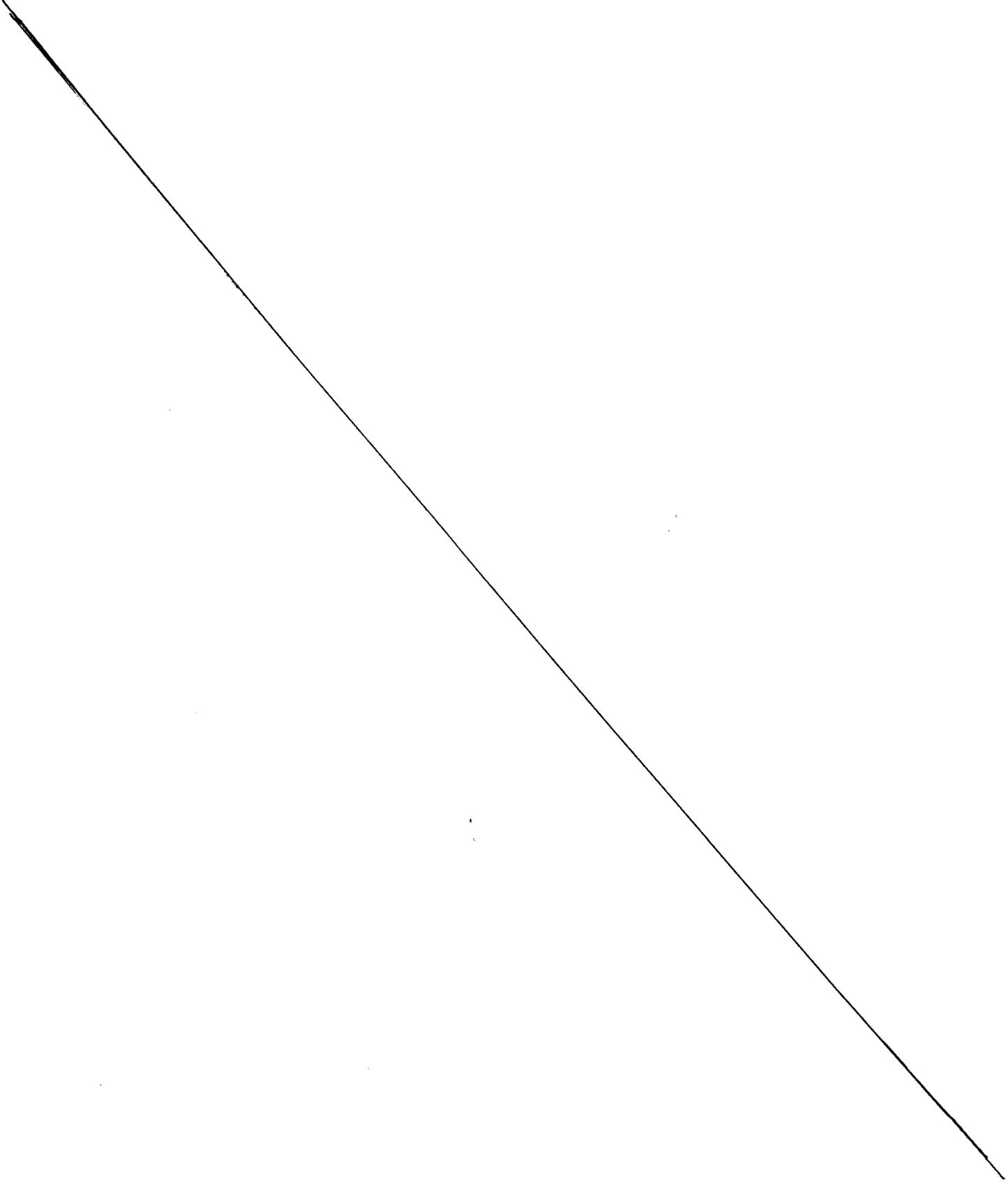
requirements for certain biotechnology and synthetic biological products subject to licensing under the PHS Act. This final rule also amended 21 CFR 600.3(t) to redefine the term “‘manufacturer” as it is used in 21 CFR 600 through 680. The definition was amended to include “‘any legal person or entity who is an applicant for a license where the applicant assumes responsibility for compliance with the applicable product and establishment standards.” This document is intended to provide guidance to those interested in the manufacture of new biological products, to those already engaged in cooperative manufacturing arrangements, and to those considering changing their present manufacturing arrangements. The guidance document may be useful to applicants submitting product, establishment, and biologics license applications and supplements.

This draft guidance represents the agency’s current thinking on cooperative manufacturing arrangements for licensed biologics. 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 statute, regulations, or both. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. Written comments may be submitted at any time, however, comments should be submitted by (*insert date 60 days after date of publication in the Federal Register*), to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document and received comments are available for public

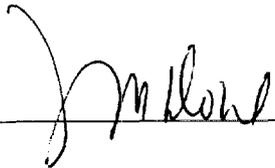
examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.



III. Electronic Access

Persons with access to the Internet may obtain the document using the World Wide Web (WWW). For WWW access, connect to CBER at "http://www.fda.gov/cber/guidelines.htm".

Dated: 7/27/99
July 27, 1999



Margaret M. Dotzel
Acting Associate Commissioner
for Policy

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