

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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[Docket No. 01D-0278]

Draft "Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research" dated August 2001. The draft guidance document discusses Type V Drug Master Files (DMF) submitted to the Center for Biologics Evaluation and Research (CBER). The draft guidance document describes the circumstances in which CBER will accept a Type V Drug Master File without a letter of intent from the DMF holder. The information in the DMF may be used to support an application or supplement, such as an investigational new drug application (IND), biologics license application (BLA), or a new drug application (NDA) submitted to CBER.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*. 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ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration,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 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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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. 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, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

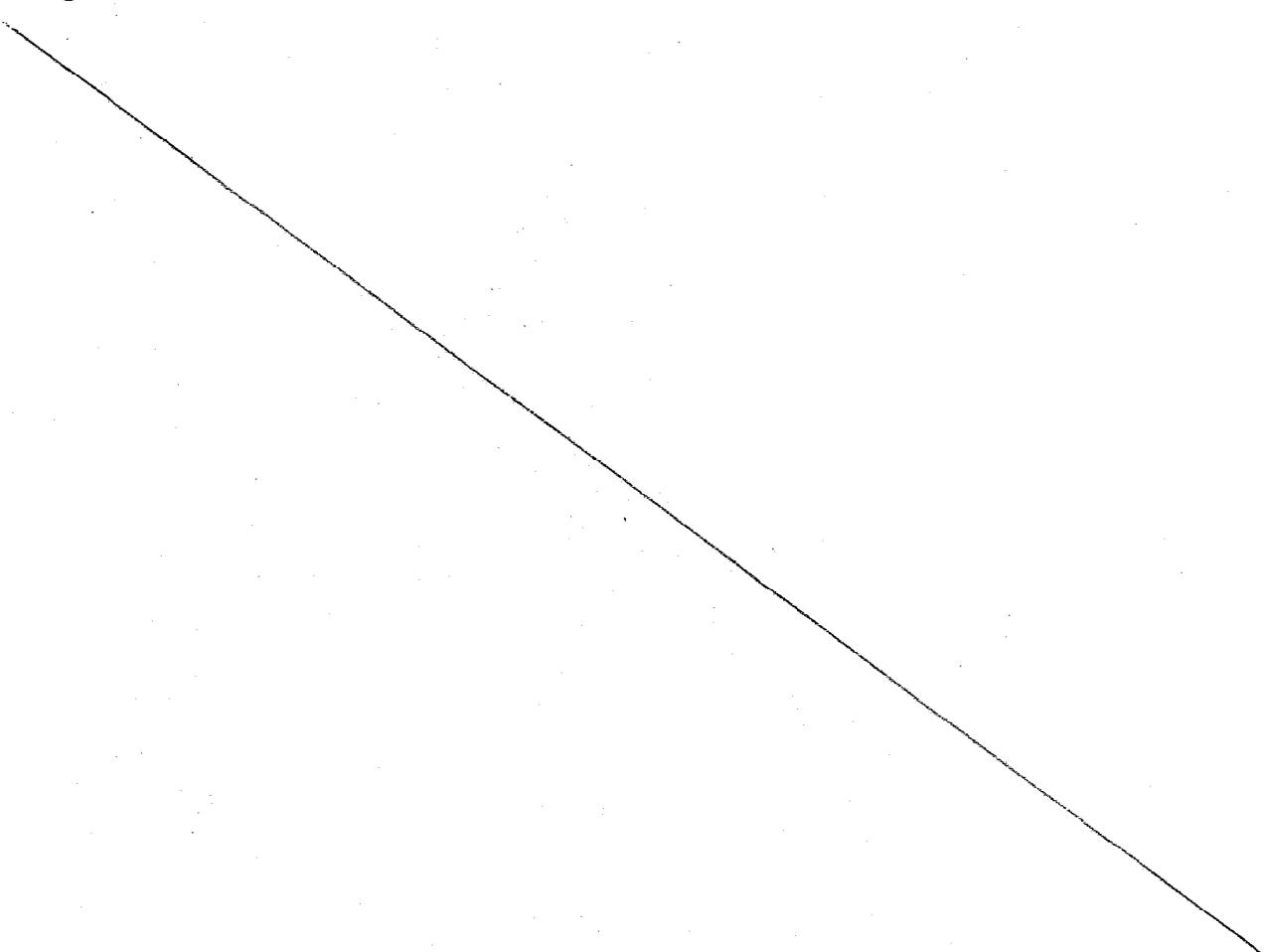
FDA is announcing the availability of a draft document entitled "Guidance for Industry: Submitting Type V Drug Master Files to the Center for Biologics Evaluation and Research" dated August 2001. The draft guidance document discusses Type V DMFs submitted to CBER. The draft guidance document describes the circumstances in which CBER will accept a Type V DMF without a letter of intent to FDA from the DMF holder. A drug master file is a submission of information to FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs and biological products. The information in the DMF may be used to support an application or supplement, such as an IND, BLA, or an NDA.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance document represents the agency's current thinking on submitting Type V Drug Master Files to CBER. 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 document 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 document. Submit written or electronic comments to ensure adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*. 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 the 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 at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 8-13-01
August 13, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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