

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Draft “Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations;” 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 FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations” dated November 2001. The draft guidance document, when **finalized**, is intended to provide information to assist FDA staff in creating and implementing effective collaborations consistent with relevant legal, ethical, and policy considerations. FDA and its stakeholders use collaborations to take advantage of and amplify the unique resources possessed by each to address a variety of public health issues. The draft guidance document enumerates factors that FDA employees should consider, and the procedures they should follow, when planning a leveraged collaboration.

DATES: Submit written or electronic comments on the draft guidance to ensure their adequate consideration in preparation of the final document by *[insert date 90 days after date of publication in the Federal Register]*.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 “Guidance for FDA: The Leveraging Handbook, An Agency Resource for Effective Collaborations” dated November 2001 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, cb0043

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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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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: Stephen M. Ripley, 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 FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations” dated November 2001. “Leveraging”, as used by FDA, describes formal or informal relationships or agreements with others outside FDA that enhance the agency’s ability to meet its public health mission. Leveraged collaborations between FDA and non-FDA partners, such as industry, academia, consumer groups, scientific experts, public health providers, States, and other government agencies, are not new to the agency. For many years, FDA has used collaborations to accomplish a wide variety of tasks related to fulfilling its public health mission. FDA is careful to structure its collaborations so that the agency’s regulatory independence, impartiality, and integrity are preserved. Successful collaborations used by FDA and its partners range in size and complexity from simple **daylong** workshops and training sessions to the creation of cooperatively administered centers that provide critical product-related safety information and expertise, i.e., the National Center for Food Safety and Technology, the Joint Initiative for Food Safety and Nutrition, and

the Product Quality Research Institute. Other collaborations involve conducting research to improve the safety, efficacy, purity, or potency of regulated products and convening experts to evaluate emerging public health issues and to recommend actions that should be taken to address the issues.

FDA held two public meetings that were announced in the **Federal Register** to discuss ways in which FDA could improve and increase collaborations with outside organizations (65 FR 8365, February 18, 2000). The meetings were held on March 23, 2000, at Stanford University, and on April 12, 2000, at Duke University. More than 300 people attended the meetings and more than 25 leveraging proposals were presented to the agency. FDA is currently reviewing the proposals. To review the transcripts of the meetings, you can visit the FDA Dockets Management Branch Web site at [http://www.fda.gov/ohrms/dockets/dockets/00n0001/00n0001 .htm](http://www.fda.gov/ohrms/dockets/dockets/00n0001/00n0001.htm).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document represents the agency's current thinking on the formation and implementation of leveraged collaborations between FDA and outside organizations. 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.

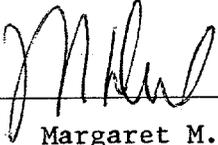
II. Comments

This 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 or electronic comments regarding this draft guidance document. Submit written 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 draft guidance document at either <http://www.fda.gov/oc/leveraging/handbook.html> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 8/31/01
August 31, 2001.



Margaret M. Dotzel,
Associate Commissioner for Policy.

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