

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D-0195]

2MB  
Display Date 3-11-03  
Publication Date 3-10-03  
Certifier R. LEDESMA

“Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations”

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

03  
MAR 10 4:11

---

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a document entitled “Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations,” dated February 2003. The guidance document 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 guidance document enumerates factors that FDA employees should consider, and the procedures they should follow, when planning a leveraged collaboration. This guidance finalizes the draft guidance under the same title dated November 2001 that was announced in the **Federal Register** on November 13, 2001.

**DATES:** Submit written or electronic comments 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, Rockville, MD 20852-1448. Send one

self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or 301-827-1800. Submit written comments on the guidance 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>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

**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 document entitled "Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations," dated February 2003. The guidance announced in this notice finalizes the draft guidance of the title dated November 2001 (67 FR 56831, November 13, 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.

This guidance is being issued consistent with FDA's good guidance practice regulation (21 CFR 10.115). The guidance document represents 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**

Interested persons may, at any time, submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the guidance document. Two copies of mailed 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 guidance 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 guidance document at <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: February 19, 2003  
February 19, 2003.



William K. Hubbard,  
Associate Commissioner for Policy and Planning.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

**BILLING CODE 4160-01-S**

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

