

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 The guidance announced in this notice finalizes the draft guidance of the title dated November 2001 (67 FR 56831, November 13, 2001).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.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03-5793 Filed 3-11-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D-0044]

Medical Devices: Draft Guidance for Industry and FDA Reviewers; Statistical Guidance on Reporting Results From Studies Evaluating Diagnostic Tests; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry and FDA reviewers entitled "Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests; Draft Guidance for Industry and FDA Reviewers." This draft guidance is regarding the submission of premarket notification and premarket approval applications (PMAs) for diagnostic tests. The draft guidance describes some statistically appropriate practices for reporting results from different studies evaluating diagnostic tests and identifies some common practices that may not provide sufficient information to support submission. Special attention is given to describing a practice called discrepant resolution and its associated problems. This draft guidance is neither final, nor is it in effect at this time.

DATES: Submit written or electronic comments on this draft guidance by June 10, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance on a 3.5" diskette to the Division of Small

Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments concerning this draft 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 information on electronic access to the draft guidance. **FOR FURTHER INFORMATION CONTACT:** Kristen L. Meier, Center for Devices and Radiological Health (HFZ-542), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-0616.

SUPPLEMENTARY INFORMATION:

I. Background

On February 11, 1998, the Center for Devices and Radiological Health (CDRH) convened a joint meeting of the Microbiology Devices Panel, Hematology and Pathology Devices Panel, Clinical Chemistry and Toxicology Devices Panel, and Immunology Devices Panel of the Medical Devices Advisory Committee. The purpose of the meeting was to obtain recommendations on

* * * appropriate data collection, analysis, and resolution of discrepant results, using sound scientific and statistical analysis to support indications for use of the in vitro diagnostic devices * * * when the new device is compared to another device, a recognized reference method or 'gold standard,' or other procedures not commonly used, and/or clinical criteria for diagnosis * * *

(63 FR 4458, January 29, 1998). Based on discussions from that meeting, this draft guidance describes some statistically appropriate practices for reporting results from different studies evaluating diagnostic tests and identifies common inappropriate practices. The draft guidance also describes a practice called discrepant resolution and its associated problems.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance document represents the agency's current thinking on statistically appropriate practices for reporting results from different studies evaluating diagnostic tests. 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