DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0044]

Guidance for Industry and Food and Drug Administration Staff; 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 the guidance entitled ''Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests.'' This guidance describes some statistically appropriate practices for reporting results from different studies evaluating diagnostic tests and identifies some common inappropriate practices. Special attention is given to describing a practice called discrepant resolution and its associated problems.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests'' 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 one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240–276–3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Kristen Meier, Center for Devices and Radiological Health (HFZ–550), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240–276–3060.

SUPPLEMENTARY INFORMATION:

I. Background

On February 11, 1998, the Center for Devices and Radiological Health (CDRH) convened a joint meeting of the Microbiology, Hematology/Pathology, Clinical Chemistry/Toxicology and Immunology Devices Panels. The purpose of this 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.'' Using the input from that meeting, a draft guidance document was developed discussing some statistically valid approaches to reporting results from evaluation studies for new diagnostic devices. The draft guidance was released for public comment on March 12, 2003.

Following publication of the draft guidance, 11 comments were submitted to FDA. Overall, comments were favorable and requested that additional information be included in the final guidance. We reviewed the comments and took their suggestions into consideration in writing this guidance, including consideration of the comments requesting greater attention to the use of standard terminology.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on reporting results from 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 approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. To receive ''Statistical Guidance on Reporting Results from Studies Evaluating Diagnostic Tests,'' you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 240–276–3151 to receive a hard copy. Please use the document number 1620 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807 have been approved under OMB Control No. 0910–0120; and the collections of information in 21 CFR part 814 have been approved under OMB Control No. 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 2, 2007.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

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