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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date 1-29-08
Publication Date 1-30-08
Certifier A. Corbin

Food and Drug Administration

[Docket No. FDA-2008-D-0031] (formerly Docket No. 2001D-0044)

Guidance for Industry and Food and Drug Administration Staff; Clinical Laboratory Improvement Amendments of 1988: Recommendations for Clinical Laboratory Improvement Amendments of 1988: Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." FDA is issuing this guidance to recommend approaches for determining whether a laboratory test may be performed by laboratories with a certificate of waiver under CLIA.

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 "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices" 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

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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.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Carol Benson, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240–276–0396.

SUPPLEMENTARY INFORMATION:

I. Background

CLIA requires that clinical laboratories obtain a certificate from the Secretary of Health and Human Services (the Secretary) before accepting materials derived from the human body for laboratory tests (42 U.S.C. 263(b)). Laboratories that perform only tests that are “simple” and that have an “insignificant risk of an erroneous result” may obtain a certificate of waiver (42 U.S.C. 263a(c)(2)). The Secretary has delegated to FDA the authority to determine under CLIA whether particular tests (waived tests) are “simple” and have “an insignificant risk of an erroneous result” (69 FR 22849, April 27, 2004). This guidance describes recommendations for device manufacturers seeking to submit information (CLIA waiver application) to FDA to support a determination that a cleared or approved in vitro diagnostic (IVD) device meets this CLIA waiver standard.

In the guidance document, FDA recommends an approach for manufacturers to demonstrate in a CLIA waiver application that a device is

simple and has an insignificant risk of erroneous result as required under CLIA (42 U.S.C. 263a). FDA based the recommendations in the guidance document on interpretation of the law, experience with CLIA complexity determinations, and comments and information from stakeholders.

The draft of this guidance was issued September 7, 2005 (70 FR 53231). FDA received and considered approximately 40 sets of comments on the draft guidance document. After taking the comments into consideration, FDA has updated the document to provide clarifications as needed. The guidance has also been revised to allow for additional supplementation of the actual patient specimens in the clinical study with alternative samples, preferably banked patient samples. The revised guidance recommends that, when neither patient specimens nor banked samples are available, it may be acceptable to supplement with other types of prepared samples, e.g., spiked, or diluted samples that mimic patient samples in terms of analyte and matrix. The revised guidance specifies that up to a total of one third of the clinical study samples may be supplemented with these types of alternative samples. The revised guidance also provides more flexibility in selecting the comparator method as well as more consistency in terms of the criteria for accuracy for waived tests as compared with moderate and high complexity tests.

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 "Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices," 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 1171 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 at <http://www.fda.gov/ohrms/dockets/default.htm>.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that 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 this guidance were approved under OMB control number 0910-0598.

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.

Please note that on January 15, 2008, the FDA Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic submissions will be accepted by FDA through FDMS only.

Dated: 1/22/08
January 22, 2008.

Jeffrey Shuren
Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S

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