Guidance for Industry and FDA Staff

Administrative Procedures for CLIA Categorization

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See additional PRA statement in Section 4 of this guidance.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostic Device Evaluation and Safety

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.regulations.gov. When submitting comments, please reference the docket number FDA-2008-D-0228**.** Comments may not be acted upon by the Agency until the document is next revised or updated.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/oivd/guidance/1143.pdf. You may also send an e-mail request to dsmica@fda.hhs.gov to receive an electronic copy of the guidance or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1143 to identify the guidance you are requesting.

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This guidance represents the Food and Drug Administration's (FDA'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. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

On February 28, 1992, the Department of Health and Human Services (DHHS) published laboratory standards regulations (57 FR 7002) implementing the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (42 U.S.C. 263a). The implementing regulations are codified at 42 CFR Part 493. CLIA regulates laboratory testing and requires that clinical laboratories obtain a certificate before accepting materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or the impairment of, or assessment of the health of human beings. The type of CLIA certificate a laboratory obtains depends upon the complexity of the tests it performs. CLIA regulations describe the following three levels of test complexity: waived tests, moderate complexity tests, and high complexity tests. 42 CFR 493.5(a).

On January 31, 2000, the responsibility for categorization of commercially available *in vitro* diagnostic (IVD) tests was transferred from the Centers for Disease Control and Prevention (CDC) to the Food and Drug Administration (FDA).[1] This allows IVD manufacturers to submit premarket notifications or applications for tests and requests for complexity categorization of these tests under CLIA to one agency.

[1] 64 FR 73561, December 30, 1999. See also the delegation to FDA to categorize commercially available in vitro diagnostic tests and perform associated functions (69 FR 22849, April 27, 2004).

This guidance document describes the general administrative procedures FDA will use to categorize tests under CLIA. This guidance does not specifically address CLIA waiver applications. For more information on CLIA waiver applications, you may refer to the guidance entitled, "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices."[2]

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/ombudsman/.

2. Procedures for Determination of CLIA Categorization

CLIA categorization of IVD tests is determined by FDA at the time of review of a premarket notification submission (510(k)) or premarket approval application (PMA) under the Federal Food, Drug, and Cosmetic Act. In cases where a 510(k) or PMA is not needed but CLIA categorization is still appropriate, manufacturers should submit a request for CLIA categorization, including a copy of the test package insert with test instructions, to FDA (see the table below for examples).

For moderate and high complexity tests, FDA determines test complexity by reviewing the package insert test instructions in the premarket submission, using the criteria listed in 42 CFR 493.17. The determination for waived tests is based on the list of tests specified as waived by regulation under 42 CFR 493.15. Manufacturers requesting CLIA waiver for tests not waived by this regulation should submit a CLIA waiver application (see Section 3, below). These applications are typically submitted after the test is cleared or approved by FDA.

[2] http://www.fda.gov/cdrh/oivd/guidance/1171.html.

In order to expedite CLIA categorization by FDA, manufacturers should submit the material described in the following table. You should address the information to CDRH's Document Mail Center (DMC), HFZ-401, 9200 Corporate Blvd., Rockville MD 20850.

In the following situations:	**The sponsor should provide:**
510(k) (Traditional or abbreviated)[3]	A copy of the package insert identified as "For CLIA categorization." The package insert that the manufacturer provides in the duplicate copy of the 510(k) can be used for this purpose.
Electronic 510(k) or PMA submissions	The electronic version of the package insert can be used for CLIA categorization. No additional information needed.
Special 510(k)[4]	A package insert identified as "For CLIA categorization." The package insert that the manufacturer provides in the duplicate copy of the 510(k) can be used for this purpose. (Note: If the device has already been categorized, it may not need re-categorization when the Special 510(k) is cleared. FDA evaluates each submission to determine if CLIA categorization is needed.)
A test that is exempt from 510(k) review	A package insert identified as: "For CLIA categorization only – 510(k) exempt device," and the classification regulation number, classification, and product code.
A test system that falls under the Replacement Reagent Policy. (See http://www.fda.gov/cdrh/oivd/guidance/950.pdf for guidance on OIVD's Replacement Reagent and Instrument Family Policy.)	A package insert identified as: "For CLIA categorization only" and a reference to the original 510(k), including the classification regulation numbers, classification, and product codes for the test and instrument.
Original PMA or PMA Supplement	A copy of the package insert identified as "For CLIA categorization." The package insert that the manufacturer provides in the duplicate copy of the submission can be used for this purpose.

[3] See guidance entitled "Format for Traditional and Abbreviated 510(k)s" at http://www.fda.gov/cdrh/ode/guidance/1567.pdf.

[4] See Device Advice page entitled "How To Prepare a Special 510(k)" at http://www.fda.gov/cdrh/devadvice/3144.html.

Additionally, FDA recommends that where the name of an approved or cleared device changes, or the name of the manufacturer or distributor changes, the manufacturer should submit the updated label to FDA so that its record of categorized tests is accurate.

FDA will notify manufacturers of the assigned complexity through written correspondence. Categorization will be effective as of the date of the written notification to the manufacturer (see 42 CFR 493.17(c)(1)(ii)). A searchable database of CLIA categorizations for IVD devices, which is updated periodically, is available at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/clia.cfm.

3. CLIA Waiver Protocols and Applications

We recommend that a manufacturer who wishes to request CLIA waiver for a device (other than those devices already waived by 42 CFR 493.15), refer to the guidance entitled, "Guidance for Industry and FDA Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices." Manufacturers have the option to submit their planned protocols or study designs to support CLIA waiver in order to obtain feedback from FDA prior to conducting the study. These planned protocols or study designs are logged in by the document mail center as "Pre-IDEs." See the FDA website for more information on the Pre-IDE process: http://www.fda.gov/cdrh/devadvice/ide/approval.shtml. Pre-IDEs for CLIA waiver should include a reference to the original 510(k) or PMA number, 2 copies of the protocol/study design, and an electronic version if available.

4. 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 time required to complete this information collection is estimated to average 900 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Carol Benson,
Center for Devices and Radiological Health (HFZ-440),
Food and Drug Administration,
2098 Gaither Road,
Rockville, MD 20850.

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR Part 801 have been approved under OMB control number 0910-0485 and the collections of information in 21 CFR Part 807, subpart E have been approved under OMB control number 0910-0120.