Guidance for Industry and/or for FDA Reviewers/Staff and/or Compliance

Guidance for Administrative Procedures for CLIA Categorization

Draft Guidance – Not for Implementation

This guidance document is being distributed for comment purposes only.
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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Division of Clinical Laboratory Devices
Office of Device Evaluation

Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

Additional Copies:

World Wide Web/CDRH home page at http://www.fda.gov/cdrh or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1143 when prompted for the document shelf number.

Guidance[1] for Administrative Procedures for CLIA Categorization

Introduction

On January 31, 2000 the responsibility for categorization of commercially marketed in vitro diagnostic (IVD) tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) was transferred from the Centers for Disease Control and Prevention (CDC) to the Food and Drug Administration (FDA). This allows manufacturers to submit premarket applications for products and requests for complexity categorization of these products under CLIA to one agency.

This document sets forth general administrative procedures FDA will use to assign a device's complexity category under CLIA regulations (42 CFR 493.17). While this document is not binding on the Agency or any person, it does represent FDA's current views on the procedures a manufacturer should follow when requesting complexity categorization for in vitro diagnostic test systems. This guidance does not create, or confer any rights, privileges, or benefits for, or on, any person. When, however, this document reiterates a requirement imposed by law or regulation, the requirement is law, and its force and effect are not changed in any way by virtue of its inclusion in this guidance.

Background

On February 28, 1992, the Department of Health and Human Services (DHHS) published the final laboratory standards regulations (57 FEDERAL REGISTER 7002) implementing CLIA (codified at 42 CFR part §493). CLIA expands regulation of laboratory testing and imposes minimum requirements to ensure the accuracy of tests, assays, or examinations of 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.

There are three levels of testing complexity:

- waived tests
- moderate complexity tests
- high complexity tests

[1] This document is intended to provide guidance. It represents the Agency's current thinking on the above. 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, regulations, or both.

Laboratories performing only waived tests are subject to minimal regulation. Laboratories performing moderate or high complexity tests are subject to specific laboratory standards governing certification, personnel, proficiency testing, patient test management, quality assurance, quality control, and inspections.

FDA Action on Submissions for CLIA Categorization

Manufacturers will be notified of the assigned complexity through routine correspondence (e.g., as an enclosure with a clearance or approval letter, or as a separate letter in response to other submissions, such as submissions to modify an IVD test or replacement reagent). Categorization will be effective as of the date of the written notification to the manufacturer (42 CFR § 493.17 (c) (1) (iii)).

Manufacturer's Documentation for Request for CLIA Categorization

In order to expedite CLIA categorization by FDA, submit the information described below to CDRH's Document Mail Center (DMC), HFZ-401, 9200 Corporate Blvd., Rockville MD 20850;

For a new 510(k) or PMA – include one extra copy of the package insert (PI) in a section identified as "FOR CLIA CATEGORIZATION" in the 510(k) or PMA submission.

For an exempt 510(k) - a request labeled "FOR CLIA CATEGORIZATION ONLY, EXEMPT DEVICE" and 2 copies of the PI with a citation of the regulation number, the classification and the product code.

For a cleared but uncategorized 510(k) - a request labeled "FOR CLIA CATEGORIZATION ONLY, PREVIOUSLY CLEARED DEVICE"; 2 copies of the PI; and reference the 510(k) number.

For an approved but uncategorized PMA (original or supplement) - a request labeled "FOR CLIA CATEGORIZATION ONLY, PREVIOUSLY APPROVED DEVICE"; 2 copies of the PI; and reference the PMA number.

Manufacturer's Documentation for Waiver Protocol and Waiver Application

For a waiver protocol - send request to DMC labeled "CLIA WAIVER PROTOCOL" and reference the original 510(k) number or PMA number, if appropriate.

For a waiver application - send request to DMC labeled "CLIA WAIVER APPLICATION" and reference the 510(k) number or PMA number, if appropriate.

These instructions are summarized in the following table.

Requests for Complexity Categorization

If Type of Submission is:	Manufacturer should provide:
510(k) Traditional	One extra copy of package insert (PI) labeled “FOR CLIA CATEGORIZATION”
510(k) Exempt	Request “ FOR CLIA CATEGORIZATION ONLY, EXEMPT DEVICE” with 2 copies of PI; provide regulation number, classification, and product code
Abbreviated 510(k) Special 510(k) Add-to-file (e.g., replacement reagent)	One extra copy of PI labeled "FOR CLIA CATEGORIZATION"
Cleared 510(k) (Uncategorized)	Request labeled "FOR CLIA CATEGORIZATION ONLY, PREVIOUSLY CLEARED DEVICE"; reference the original 510(k) number, and provide 2 copies of PI
Original PMA PMA Supplement	One extra copy of PI labeled "FOR CLIA CATEGORIZATION "
Approved Original PMA or PMA Supplement Uncategorized	Request labeled "FOR CLIA CATEGORIZATION ONLY, PREVIOUSLY APPROVED DEVICE ": reference the PMA number, and provide 2 copies of PI
Waiver Protocol	Request labeled “CLIA WAIVER PROTOCOL”; reference the original 510(k) or PMA number if appropriate; and provide 2 copies of the protocol
Waiver Application	Request labeled "CLIA WAIVER APPLICATION"; reference the original 510(k) or PMA number if appropriate, and send 2 copies of the protocol