

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

DMB

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[Docket No. 00D-1401]

**Draft Guidance for Industry on Administrative Procedures for CLIA Categorization; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry entitled "Guidance for Administrative Procedures for CLIA Categorization." The Center for Devices and Radiological Health is issuing this draft guidance document to provide information to manufacturers on how to submit requests for complexity categorization under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and how FDA will notify the manufacturer of the complexity categorization.

**DATES:** Submit written comments on the draft guidance document by *[insert date 90 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written requests for single copies on a 3.5" diskette of the draft guidance document entitled "Guidance for Administrative Procedures for CLIA Categorization" to the Division of Small Manufacturers Assistance (HFZ-220), Center for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 Submit written comments concerning this draft guidance document to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets

in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Clara A. Sliva, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-827-0496.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

On January 31, 2000, the responsibility for categorization of commercially marketed products under CLIA was transferred from the Centers for Disease Control and Prevention (CDC) to FDA. This allows manufacturers to submit premarket applications for products and requests for complexity categorization of these products under CLIA to one agency. This draft guidance document contains information on the administrative procedures that the manufacturers of in vitro diagnostic products will use to receive a complexity categorization under CLIA from FDA.

**II. Significance of Guidance**

This draft guidance document represents the agency's current thinking on the administrative procedures for CLIA categorization of commercially marketed in vitro diagnostic products. 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 applicable statute, regulations, or both.

The agency has adopted good guidance practices (GGP's), which set forth the agency's policies and procedures for the development, issuance, and use of guidance documents (62 FR 8961, February 27, 1997). This guidance document is issued as Level 1 guidance consistent with GGP's.

### III. Electronic Access

In order to receive the draft guidance document entitled “Guidance for the Administrative Procedures for CLIA Categorization” via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (1143) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance document may also do so using the Internet. The Center for Devices and Radiological Health (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 access to the Internet. Updated on a regular basis, the CDRH home page includes “Guidance for Administrative Procedures for CLIA Categorization,” device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers’ addresses), small manufacturers’ assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at <http://www.fda.gov/cdrh>. The draft guidance document entitled “Guidance on the Administrative Procedures for CLIA Categorization” will be available at <http://www.fda.gov/cdrh//ode/guidance/1143.pdf>

### IV. Comments

Interested persons may, on or before *[insert date 90 days after date of publication in the Federal Register]*, submit to Dockets Management Branch (address above) written comments regarding this draft guidance document. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number

found in brackets in the heading of this document. The draft guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 8/1/00  
August 1, 2000

Linda S. Kahan

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COPY OF THE ORIGINAL**

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