TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of the 2007 Amendments	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total Hours						30,796

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.
[3] Annual increase in burden.

The estimates in table 1 of this document are based on FDA's experience, data from the device registration and listing database, and our estimates of the time needed to complete the previously required forms. We estimate that the time needed to enter registration and listing information electronically using FDA Form 3673 will not differ significantly from the time needed to fill in the paper forms (FDA Forms 2891, 2891a, and 2892) that previously were used for this purpose because the information required is essentially identical.

In addition, under section 224 of FDAAA, device establishments owner/operators for whom registering and listing by electronic means is not reasonable may request a waiver from the Secretary. Because a device establishment's owner/operator required to register and list would only need to have access to a computer, Internet, and an e-mail address for registration and list by electronic means, the agency did not anticipate the receipt of a large number of requests for waiver. For the first few months of operation of the web-based system, i.e., October through December 2007, FDA received fewer than 10 requests for waivers from the requirement to submit registration and listing information electronically. As data for more than 16,000 establishments have been received electronically for the same period, these requests amount to less than 1 percent of the total number of establishments that have responded.

Based on information taken from our databases, FDA estimates that there are 29,370 owner/operators who collectively register a total of 33,490 device establishments. The number of respondents listed for section 224 of FDAAA in the burden table is 29,370, which corresponds to the number of owner/operators who annually register one or more establishments. In addition, FDA estimates that 4,988 owner/operators are initial importers who must register their establishments but who, under FDA's existing regulations, are not required to list their devices unless they initiate or develop the specifications for the devices or repackage or relabel the devices. The number of respondents included in the burden table for section 223 of FDAAA is 24,382, which corresponds to the number of owner/operators who list one or more devices annually (29,370 - 4,988 = 24,382).

To calculate the burden estimate for waiver requests under section 224 of FDAAA, we assume as stated previously that less than one tenth of one percent of the 33,490 total device establishments would request waivers from FDA. This means the total number of waiver requests would probably not exceed 20 requests (33,490 x 0.0006). We also estimate that the one-time burden on these establishments would be an hour of time for a mid-level manager to draft, approve, and mail a letter. In addition, FDA estimates the total number of establishments will increase by 2,600 new establishments each year. Of the 2,600 new registrants each year, we assume that less than one percent (i.e., 1) of these will also request waivers each year. The total, therefore, is 21 waiver requests, which could increase by only 1 additional request each year.

Dated: May 1, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0228] (formerly Docket No. 00D–1401)

Guidance for Industry and Food and Drug Administration Staff; Administrative Procedures for CLIA Categorization; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Administrative Procedures for CLIA Categorization.'' The guidance describes FDA's current practices concerning the administrative aspects of categorizing commercially available in vitro diagnostic tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The guidance discusses what manufacturers should submit to help expedite CLIA categorization by FDA.

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 ''Administrative Procedures for CLIA Categorization'' 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 the 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.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, 240–276–0491, ext. 117.

SUPPLEMENTARY INFORMATION:

I. Background

On February 28, 1992, the Department of Health and Human Services published the final laboratory standards regulations (57 FR 7002) implementing 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 three levels of test complexity: Waived tests, moderate complexity tests, and high complexity tests.

On January 31, 2000, the responsibility for categorization of commercially marketed in vitro diagnostic (IVD) tests was transferred from the Centers for Disease Control and Prevention to FDA (64 FR 73561, December 30, 1999). This allows IVD test manufacturers to submit premarket (510(k)) notifications or applications and requests for complexity categorization under CLIA to one agency. This notice announces the availability of a guidance document that describes the general administrative procedures FDA uses to assign a device's complexity category under CLIA.

The draft of this guidance was issued August 14, 2000, and the comment period closed on November 13, 2000. FDA did not receive any comments concerning the ''Draft Guidance on Administrative Procedures for CLIA Categorization.'' In preparing the final guidance, however, FDA needed to obtain an approval for a new collection of information from the Office of Management and Budget (OMB). We obtained this approval (see section IV. Paperwork Reduction Act of 1995) and are now issuing the final guidance. Updates added to the guidance include a revised background section and procedures for CLIA categorization for 510(k) submissions submitted electronically. The guidance also notes that manufacturers who wish to request CLIA waiver for a device (other than those devices already waived under 42 CFR 493.15), should 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,'' issued in January 2008.

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 administrative procedures for CLIA categorization. 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 ''Administrative Procedures for CLIA Categorization,'' 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 1143 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.regulations.gov*.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by 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 0910–0607.

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 Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at *http://www.regulations.gov*.

Dated: April 30, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Office of Biotechnology Activities; Recombinant DNA Research; Notice of a Meeting of an NIH Blue Ribbon Panel

There will be a meeting of the NIH Blue Ribbon Panel to advise on the Risk Assessment of the National Emerging Infectious Diseases Laboratories (NEIDL) at Boston University Medical Center. The meeting will be held on Friday, May 16, 2008, at The Commonwealth of Massachusetts Bureau of State Office Buildings, State House, Gardner Auditorium, 24 Beacon Street, Boston, Massachusetts 02133, from approximately 9 a.m. to 12 p.m.

Discussions will include the charge to the Panel and the process and framework for deliberations. There will also be time allotted on the agenda for public comment. Sign up for public comment will begin at approximately 8 a.m. on May 16, 2008. In the event that time does not allow for all those interested to present oral comments, anyone may file written comments using the address below.

To file written comments or for further information concerning this meeting contact Ms. Laurie Lewallen, Advisory Committee Coordinator, Office of Biotechnology Activities, Office of the Director, National Institutes of Health, Mail Stop Code 7985, Bethesda, MD 20892–7985, 301–496–9838, *lewallla@od.nih.gov*

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed above in advance of the meeting. Any interested person may file written comments with the panel by forwarding the statement to the Contact Person listed on this notice. The statement should include the name,