

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹—Continued

Activity	No. of Record-keepers	Annual Frequency per Record-keeping	Total Annual Records ²	Hours per Records	Total Hours
Total					450

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

² For purposes of estimating number of records and hours per record, a "record" means all records kept for an individual reportable food by the responsible party or a voluntary reporter.

Dated: October 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-25100 Filed 10-19-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0487]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on guidance on informed consent for in vitro diagnostic device studies using leftover human specimens that are not individually identifiable.

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the

docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance on Informed Consent For In Vitro Diagnostic Device Studies Using Leftover Human Specimens That Are Not Individually Identifiable—OMB Control Number 0910-0582—Extension

FDA's investigational device regulations are intended to encourage the development of new, useful devices in a manner that is consistent with public health, safety, and with ethical standards. Investigators should have freedom to pursue the least burdensome means of accomplishing this goal. However, to ensure that the balance is maintained between product development and the protection of public health, safety, and ethical standards, FDA has established human subject protection regulations addressing requirements for informed consent and institutional review board (IRB) review that apply to all FDA-regulated clinical investigations involving human subjects. In particular, informed consent requirements further both safety and ethical considerations by allowing potential subjects to consider both the physical and privacy risks they face if they agree to participate in a trial.

Under FDA regulations, clinical investigations using human specimens conducted in support of premarket submissions to FDA are considered human subject investigations (see 21 CFR 812.3(p)). Many investigational device studies are exempt from most provisions of part 812 (21 CFR part 812), Investigational Device Exemptions, under § 812.2(c)(3), but FDA's regulations for the protection of human subjects (21 CFR parts 50 and 56) apply to all clinical investigations that are regulated by FDA (see 21 CFR 50.1; 21 CFR 56.101, 21 U.S.C. 360j(g)(3)(A), and 21 U.S.C. 360j(g)(3)(D)).

FDA regulations do not contain exceptions from the requirements of informed consent on the grounds that the specimens are not identifiable or that they are remnants of human specimens collected for routine clinical care or analysis that would otherwise have been discarded. Nor do FDA regulations allow IRBs to decide whether or not to waive informed

consent for research involving leftover or unidentifiable specimens.

In a level one guidance document issued under the Good Guidances Practices regulation, 21 CFR 10.115,

FDA outlines the circumstances in which it intends to exercise enforcement discretion as to the informed consent regulations for

clinical investigators, sponsors, and IRBs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN

FD&C Act Section:	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
520(g)	700	1	700	4	2,800	\$210,000	\$420,000

The recommendations of this guidance impose a minimal burden on industry. FDA estimates that 700 studies will be affected annually. Each study will result in one recordkeeping per year, estimated to take 4 hours to complete. This results in a total recordkeeping burden of 2,400 hours (700 x 4 = 2,800). FDA estimates that the cost of developing standard operating procedures for each record keeper is \$300 (6 hours of work at \$50/hour (h)). This results in a total cost to industry of \$210,000 (\$300 x 700 recordkeepers). FDA estimates that operating costs for collecting this information is \$300 per record keeper (6 hours of work at \$50/h). This results in a total operational and maintenance cost to industry of \$210,000 (\$300 x 700 recordkeepers). The total cost of this recordkeeping, capital plus operational and maintenance cost is estimated to be \$420,000.

Dated: October 13, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0489]

Agency Information Collection Activities; Proposed Collection; Comment Request; Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to

publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension, of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on collections of information associated with the guidance issued January 30, 2008, and titled "Recommendations: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices".

DATES: Submit written or electronic comments on the collection of information by December 21, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications—21 CFR Section 493 (OMB Control Number 0910-0598)—Extension

Congress passed the Clinical Laboratory Improvements Amendment (CLIA) (Public Law 100-578) in 1988 to establish quality standards for all laboratory testing. The purpose was to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test took place. 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. 263a(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 whether particular tests (waived tests) are "simple" and have "an insignificant risk of an erroneous result" under CLIA (69 FR 22849, April 27, 2004). This