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.

[FR Doc. E9–25178 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–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.

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.

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

guidance document describes recommendations for device manufacturers submitting to FDA an application for determination that a cleared or approved device meets this CLIA standard (CLIA waiver application).

The guidance recommends that CLIA waiver applications include a description of the features of the device that make it ''simple''; a report describing a hazard analysis that identifies potential sources of error, including a summary of the design and results of flex studies and conclusions drawn from the flex studies; a description of fail-safe and failure alert mechanisms and a description of the studies validating these mechanisms; a description of clinical tests that demonstrate the accuracy of the test in the hands of intended operators; and statistical analyses of clinical study results. Only new information collections not already approved are included in the estimate in the following table. Quick reference instructions are a short version of the instructions that are written in simple language and that can be posted.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours	Operating and Maintenance Costs
493.15(a) and (b)	40	1	40	780	31,200	$50,200

[1] There are no capital costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Operating and Maintenance Costs
493.15(a) and (b)	40	1	40	2,800	112,000	$16,000

[1] There are no capital costs associated with this collection of information.

The total number of reporting and recordkeeping hours is 143,200 hours. FDA bases the burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests. Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to submit one CLIA waiver application per year. The time required to prepare and submit a waiver application, including the time needed to assemble supporting data, averages 780 hours per waiver application for a total of 31,200 hours for reporting. Based on previous years experience with CLIA waiver applications, FDA expects that each manufacturer will spend 2,800 hours creating and maintaining the record for a total of 112,000 hours.

The total operating and maintenance cost associated with the waiver application is estimated at $66,200. The cost consists of specimen collection for the clinical study (estimated $23,500); laboratory supplies, reference testing and study oversight (estimated $26,700); shipping and office supplies (estimated $6,000); and educational materials, including quick reference instructions (estimated $10,000).

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 801 and § 809.10 have been approved under OMB control number 0910–0485 and the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437.

Dated: October 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–25177 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–D–0490]

Draft Guidance for Industry and Food and Drug Administration Staff: Investigational New Drug Applications for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for Industry and FDA Staff: Investigational New Drug Applications (INDs) for Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications,'' dated October 2009. In this draft guidance, we refer to these products for hematopoietic reconstitution for specified indications as hematopoietic progenitor cells, cord (HPC–C). This draft guidance provides advice to potential sponsors (e.g., generally cord blood banks, or registries, and individual physicians serving as sponsor-investigators) to assist in the submission of an IND for certain HPC–Cs, when such HPC–Cs are not licensed in accordance with certain FDA regulations, and when a suitable human leukocyte antigen (HLA) matched cord blood transplant is needed for treatment of a patient with a serious or life-threatening disease or condition and there is no satisfactory alternative treatment. This draft guidance document is applicable only to HPC–Cs intended for hematopoietic reconstitution in patients with the clinical indications listed in the guidance entitled ''Guidance for Industry: Minimally Manipulated, Unrelated Allogeneic Placental/Umbilical Cord Blood Intended for Hematopoietic Reconstitution for Specified Indications'' (HPC–C licensure guidance), published elsewhere in this issue of the **Federal Register**. FDA is also announcing that it no longer intends to exercise enforcement discretion with respect to the IND and biologics license application (BLA) requirements for minimally manipulated, unrelated allogeneic hematopoietic stem/progenitor cell products and the phase-in implementation period for IND and license application requirements will end as of October 20, 2011.