FDA carefully considers the benefits such agreements will provide to the public. The cooperative agreement ensures FDA's continued participation and support in the Annual Environmental Design Contest. Through a mix of science and engineering, it creates new resources and stimulates new and timely solutions to real world environmental problems.

II. Eligibility Information

Competition is limited to WERC because it is a unique educational opportunity and is the only college level competition of its kind.

WERC, a Consortium for Environmental Education and Technology Development, a program of the College of Engineering at New Mexico State University, was established in 1990 under a cooperative agreement with the U.S. Department of Energy. Starting in 1991, WERC has conducted an Annual Environmental Design Contest which is a unique educational experience for students from throughout the world. The contest provides an opportunity for students to address real world environmental and food safety related problems, experience a team developed project, publish research papers, and network with experts and potential employers. The contest is open to any 2-year, 4-year, or graduate degree institution. A high school-level competition has been held concurrently with the university contest since 1997. Many of the tasks deal with waste disposal, ground water contamination, nuclear waste treatment, and similar subjects; however in 2001, a food safety track was added and the contest was broadened to include disciplines such as microbiology and chemical contaminants in foods. The FDA has supported this program since Fiscal Year 2000. This notice confirms FDA's intent to fund for another 5-year project period.

As of October 1, 2003, applicants are required to have a Dun and Bradstreet Number (DUNS) to apply for a grant or cooperative agreement from the Federal Government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1–866–705–5711. You should identify yourself as a Federal grant applicant when you contact Dun and Bradstreet, Inc.

III. Application and Submission

For further information or a copy of the complete Request for Applications (RFA) contact Cynthia Polit, Grants Management Specialist, Division of Contracts and Grants Management (HFA–500), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7180, e-mail: *cynthia.polit@fda.gov* or *cpolit@oc.fda.gov*. This RFA can be viewed on Grants.gov under ''Grant Find.'' A copy of the complete RFA can also be viewed on the FDA/CFSAN website at *http://www.cfsan.fda.gov/list.html*. For issues regarding the programmatic aspects of this notice: Wendy Buckler, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1926, email: *wendy.buckler@fda.gov*.

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17731 Filed 9–6–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2001D–0044]

Draft Guidance for Industry and Food and Drug Administration Staff: Recommendations for Clinical Laboratory Improvement Amendments of 1988 Waiver Applications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications.'' FDA is issuing this draft guidance to recommend an approach for determining whether a laboratory test may be performed by laboratories with a certificate of waiver under CLIA. This draft guidance replaces the previous draft guidance entitled ''Guidance for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver,'' March 1, 2001.

DATES: Submit written or electronic comments on this draft guidance by December 6, 2005. Submit written comments on the information collection provisions by November 7, 2005.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) for Waiver Applications'' 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 that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this draft guidance and the information collection provisions 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.fda.gov/dockets/ecomments*. 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, 9200 Corporate Blvd., Rockville, MD 20850, 240–276–0443, ext. 144.

SUPPLEMENTARY INFORMATION:

I. Background

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. 263(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 under CLIA whether particular tests (waived tests) are ''simple'' and have ''an insignificant risk of an erroneous result'' (April 27, 2004, 69 FR 22849). This draft 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).

FDA previously issued a draft guidance entitled ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Criteria for Waiver'' on March 1, 2001. This new draft guidance replaces the previous draft guidance.

The changes compared to the previous draft guidance include the following: (1) Greater emphasis on scientifically-based flex studies and validation studies, linked to the hazard analysis for each device; (2) recognition that reference methods may not be

available for every device type (although devices should be traceable to methods of known accuracy when true reference methods are available); (3) additional emphasis on use of quality control procedures; (4) greater emphasis on intended users during studies testing the device; and (5) updated study recommendations with emphasis on use of patient specimens, in an intended use environment, over time.

FDA bases the recommendations in this draft guidance on its interpretation of CLIA, FDA's experience with CLIA complexity determinations, and the agency's interactions with stakeholders. One of the interactions with stakeholders was at an open public workshop on August 14 and 15, 2000. In addition, a proposal presented by (Advanced Medical Technology Association) AdvaMed at the September 2003 Clinical Laboratory Improvement Advisory Committee (CLIAC) meeting, and recommendations proposed by CLIAC during the February 2004 meeting were considered in the development of this guidance.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance when finalized will represent the agency's current thinking on recommendations for CLIA Waiver Applications. 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

To receive ''Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *gwa@cdrh.fda.gov* to receive a hard copy or an electronic copy. Please use the document number (1171) to identify the guidance you are requesting.

Persons interested in obtaining a copy of the draft guidance may also do so by using the Internet. 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 on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (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 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 the following 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.

Title: Recommendations for CLIA Waiver Applications

Description: Congress passed the 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 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). 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. The guidance also makes recommendations concerning labeling of waived tests. The burden associated with most of these labeling recommendations is approved under OMB control number 0910–0485. Only new information collections not already approved are included in the estimate below. The recommendation for quick reference instructions is a new information collection which FDA is submitting to OMB for review. Quick reference instructions are a short version of the instructions that are written in simple language and that can be posted. The guidance also notes that waived tests remain subject to applicable reporting and recordkeeping requirements under 21 CFR part 803. The burden associated with this provision is approved under OMB control number 0910–0437.

Respondents to this collection of information are manufacturers of in vitro diagnostic devices.

FDA estimates the burden of this collection as follows.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per response	Total Hours	Operating and Maintenance Costs
40	1	40	780	31,200	$5,500

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Record	Total Hours	Operating and Maintenance Costs
40	1	40	2,800	112,000	$60,700

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

Based on previous years' experience with CLIA waiver applications, FDA expects 40 manufacturers to apply for one CLIA waiver per year. The annual reporting burden to respondents is estimated to be 31,200 hours, and recordkeeping burdens for respondents is estimated to be 112,000 hours. FDA based the reporting and recordkeeping burden on an agency analysis of premarket submissions with clinical trials similar to the waived laboratory tests.

The total operating and maintenance cost associated with the implementation of this draft guidance is estimated to be $66,200. The cost consists of specimen collection for the clinical study (estimated at $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 ($10,000).

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.

Dated: August 31, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–17732 Filed 9–1–05; 4:00 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0334]

Draft Guidance for Industry on the Pediatric Research Equity Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''How to Comply with the Pediatric Research Equity Act.'' This draft guidance provides recommendations on how to interpret the requirements of the Pediatric Research Equity Act (PREA), which requires pediatric studies of certain drugs and biological products to ensure that those products that are likely to be commonly used in children or that represent a meaningful therapeutic benefit over existing treatments contain adequate pediatric labeling for approved indications.

DATES: Submit written or electronic comments on the draft guidance by November 7, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Submit written comments on the draft 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.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

Grace Carmouze, Center for Drug Evaluation and Research (HFD–950), Food and Drug Administration,5600 Fishers Lane, Rockville, MD 20857, 301–594–2041, or

Leonard Wilson, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, suite 200N Rockville, MD 20852–1448, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''How to Comply with the Pediatric Research Equity Act.'' On December 3, 2003, the Pediatric Research Equity Act was signed into law. PREA amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 505B (21 U.S.C. 355B). In PREA, Congress codified many of the elements of the Pediatric Rule, a final rule issued by FDA on December 2, 1998 (63 FR 66632), and suspended by court order on October 17, 2002. *Association of American Physicians, and Surgeons, Inc.* v. *FDA*, 226 F. Supp. 2d 204 (D.D.C. 2002). Specifically, PREA, in adding section 505B(a) of the act, requires all applications (or supplements to an application) submitted under section 505 of the act (21 U.S.C. 355) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262) for a new active ingredient, new indication, new dosage form, new dosing regimen, or