

Estimated Total Annual Burden Hours: 750.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: *infocollection@acf.hhs.gov*. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the

information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 23, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 08-382 Filed 1-29-08; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Adoption and Foster Care Analysis Reporting System for title IV-B and title IV-E.

OMB No. 0980-0267.

Description: Section 479 of title IV-E of the Social Security Act (the Act) directs States to establish and implement an adoption and foster care reporting system. Federal regulations at 45 CFR 1355.40 sets forth the requirements of section 479 of the Social Security Act for the collection of uniform, reliable information on children who are under the responsibility of the State title IV-B/IV-E agency for placement, care, and adoption. The respondents are child welfare agencies in the 50 States, the District of Columbia, and Puerto Rico. The data collected will inform State/Federal policy decisions, program management, and responses to Congressional and Department inquiries. Specifically, the data are used for short/long-term budget projections, trend analysis, child and family service reviews, and to target areas for improved technical assistance. The data will provide information about foster care placements, adoptive parents, length of time in care, delays in termination of parental rights and placement for adoption.

Respondents: States, District of Columbia and Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS (Electronic Submission)	52	2	3,005	312,513

Estimated Total Annual Burden Hours: 312,513.

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the

proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: January 23, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 08-383 Filed 1-29-08; 8:45 am]

BILLING CODE 4184-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Office of Community Services (OCS) Evaluation Initiatives: Community Economic Development (CED) and Job Opportunities for Low-Income (JOLI) Individuals.

OMB No.: 0970-0317.

Description: The Office of Community Services (OCS) is a component of the Administration for Children and Families (ACF), which is part of the U.S. Department of Health and Human Services (HHS). Part of OCS' responsibilities is the program administration of Federal grants awarded through an annual competitive process to support urban and rural community economic development projects carried out by local, non-profit, community-based organizations. The legislative requirement for these two

programs is in Title IV of the Community Opportunities, Accountability and Training and Educational Services Act (COATS Human Services Reauthorization Act) of

October 27, 1998, Pub. L. 105–285, section 680(b) as amended. The questionnaire will collect information concerning its outcomes and management. OCS will use the data to

critically review the overall design and effectiveness of each program.

Respondents: OCS Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Questionnaire for OCS–JOLI Grantees in the US	25 JOLI grantees	1	1.5	37.5
Questionnaire for OCS–CED Grantees in the US	147 CED grantees	1	1.5	220.5

Estimated Total Annual Burden Hours:

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: infocollection@acf.hhs.gov.

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following:

Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: January 23, 2008.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. 08–384 Filed 1–29–08; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0031] (formerly Docket No. 2001D–0044)

Guidance for Industry and Food and Drug Administration Staff; Clinical Laboratory Improvement Amendments of 1988: Recommendations for Clinical Laboratory Improvement Amendments of 1988: Waiver Applications for Manufacturers of In Vitro Diagnostic Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices.” FDA is issuing this guidance to recommend approaches for determining whether a laboratory test may be performed by laboratories with a certificate of waiver under CLIA.

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 “Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for Manufacturers of In Vitro Diagnostic Devices” 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 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, 240–276–0396.

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” (69 FR 22849, April 27, 2004). This guidance describes recommendations for device manufacturers seeking to submit information (CLIA waiver application) to FDA to support a determination that a cleared or approved in vitro diagnostic (IVD) device meets this CLIA waiver standard.

In the guidance document, FDA recommends an approach for manufacturers to demonstrate in a CLIA waiver application that a device is simple and has an insignificant risk of erroneous result as required under CLIA (42 U.S.C. 263a). FDA based the recommendations in the guidance