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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–16842 Filed 7–12–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Renewal of Office of Community Services (OCS) Community Economic Development (CED) Standard Reporting Format

OMB No.: 0970–0386

Description: The Office of Community Services (OCS) will continue collecting key information about projects funded through the Community Economic Development (CED) program. The legislative requirement for this program is in Title IV of the Community Opportunities, Accountability and Training and Educational Services Act (COATS Human Services Reauthorization Act) of October 27, 1998, Public Law 105–285, section 680(b) as amended. The reporting format, Performance Progress Report (PPR), collects information concerning the outcomes and management of CED projects. OCS will use the data to critically review the overall design and effectiveness of the program.

The PPR will continue to be administered to all active grantees of the CED program. Grantees will be required to use this reporting tool for their semi-annual reports to be submitted twice a year. The current PPR replaced both the annual questionnaire and other semi-annual reporting formats, which resulted in an overall reduction in burden for the grantees while significantly improving the quality of the data collected by OCS. OCS seeks to renew this PPR to continue to collect quality data from grantees. To ensure the burden on grantees is not increased, all questions on the current PPR will remain the same—we propose adding only one question to the PPR regarding the total number of jobs grantees are creating with grant funds. Many grantees have asked about this element on the current PPR and currently do not have a place to report that information. This is information that most grantees are already collecting. Adding this field will allow grantees to provide this information in a consistent format and allow OCS to more accurately reflect the total number of jobs created through the CED program. Since grantees are already familiar with the current format and elements, and all questions on the PPR will remain the same (with one added question based on grantee feedback), there will be no additional burden on grantees.

Respondents: Current CED grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Questionnaire for current OCS–CED grantees	170	2	1.50	510

Estimated Total Annual Burden Hours: 510

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 Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email 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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2013–16874 Filed 7–12–13; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0375]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by August 14, 2013.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0131. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Daniel Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–5156, *Daniel.Gittleson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150(e) (OMB Control Number 0910–0131)—Extension

Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations in § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms. Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) Instructions for maintaining accountability of the number of units in each shipment, (2) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (3) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (§ 801.150(a)(2)).

The respondents to this collection of information are device manufacturers and contract sterilizers. FDA's estimate of the reporting burden is based on actual data obtained from industry over the past several years where there are approximately 90 firms subject to this requirement. It is estimated that each of these firms on the average prepares 20 written agreements each year. This estimate varies greatly, from 1 to 100, because some firms provide sterilization services on a part-time basis for only one customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a customary and usual business practice. On the average, the total annual recordkeeping burden is 7,200 hours.

The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the actual reporting requests which were required under the reporting section of this collection. To fulfill this requirement, FDA estimates it will take about 30 minutes to copy each package, for a total of 900 recordkeeping hours.

In the **Federal Register** of April 5, 2013 (78 FR 20658), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Agreement and labeling requirements, § 801.150(e)	90	20	1,800	4	7,200

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average Burden per Recordkeeping	Total hours
Record retention, § 801.150(a)(2)	90	20	1,800	[2] 0.5	900

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16867 Filed 7–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0812]

Electronic Study Data Submission; Data Standard Support; Availability of the Center for Drug Evaluation and Research Data Standards Program Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing the availability of the CDER Data Standards Strategy (version 1.0) and the CDER Data Standards Strategy—Action Plan (version 1.0). This action is being taken to ensure that all interested stakeholders are aware that the data standards program documents are available and is intended to increase awareness of CDER's data standards plans, ongoing projects, and avenues of communication. Comments may be submitted to the email address listed below.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1100, Silver Spring, MD 20993, 301–796–3800; email: *CDERDataStandards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

On December 5, 2012, the CDER Data Standards Strategy (version 1.0) was released. Its purpose is to reinforce FDA's ongoing commitment to the development, implementation, and maintenance of a comprehensive data standards program to facilitate the efficient and effective review of regulatory submissions so that safe and effective products can get to market sooner. It is aligned with the objectives of FDA's Strategic Plan and the performance goals of the Prescription Drug User Fee Act V Reauthorization as captured in the FDA Safety and Innovation Act. The CDER Data Standards Strategy supersedes version 1.1 of the CDER Data Standards Plan, which was issued in December 2010.

The first release of the companion document to the Data Standards Strategy, the CDER Data Standards Strategy—Action Plan, was issued on March 20, 2013. The Action Plan provides internal and external stakeholders with an overview and progress of current relevant data standards initiatives. The plan will be updated quarterly to indicate progress of current projects as well as initiation of new projects.

These documents are available from the CDER Data Standards Program Web site at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm.*

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–16861 Filed 7–12–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement to Support the World Trade Organization's Standards and Trade Development Facility

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2013 (FY 2013) to the World Trade Organization's (WTO) Standards and Trade Development Facility (STDF).

DATES: Important dates are as follows:

1. The application due date is August 1, 2013.
2. The anticipated start date is September 2013.
3. The expiration date is August 2, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: *Scientific/Programmatic Contact:* Julie Moss, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2031, email: *julie.moss@fda.hhs.gov.*

Grants Management Contact: Kimberly Pendleton Chew, Office of Acquisitions and Grant Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301–827–9363, email: *kimberly.pendleton@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–036

93.103

A. Background

The STDF is a unique global partnership established by the Food and Agriculture Organization, World Organization for Animal Health, World Bank, World Health Organization (WHO) and the WTO. The STDF supports developing countries in building their capacity to implement international sanitary and phytosanitary (SPS) standards, guidelines, and recommendations as a means to improve their human, animal, and plant health status and ability to gain or maintain access to markets. In achieving its aims, the STDF acts as both a coordinating and a financing mechanism.

The STDF is a widely established knowledge platform for information exchange, sharing experiences and the identification and dissemination of good practice on SPS-related technical cooperation. Since 2004, over 60 projects and 52 project preparation grants have assisted developing countries to overcome SPS constraints, and gain and maintain market access. Over 50% have benefited least developed and other low-income countries.

The STDF utilizes a key decision-support tool, Multi-Criteria Decision Analysis (MCDA), to help establish SPS priorities and ensure resources are used as efficiently as possible. The use of the MCDA tool is unique within the STDF and is a highly-valued attribute; the MCDA tool facilitates an open and transparent discussion among public and private stakeholders about capacity-building needs and resources. The STDF is committed to the Paris Principles on Aid Effectiveness and to achieving the Millennium Development Goals.

With an increasingly diverse and complex global food supply, FDA's interest is to strengthen food safety systems globally to prevent food safety