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. 2013–29767 Filed 12–13–13; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Submission for OMB Review; Comment Request

*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.

### Additional Information

Copies of the proposed collection may be obtained 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. All requests should be identified by the title of the information collection. Email 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, Email: *OIRA_SUBMISSION@OMB.EOP.GOV.* Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2013–29798 Filed 12–13–13; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2013–D–0117]**

### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act

**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 January 15, 2014.

**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-New and title ''Providing Information About Pediatric Uses of Medical Devices Under Section 515A of the Federal Food, Drug, and Cosmetic Act''. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@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.

**Medical Devices; Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure—(OMB Control Number 0910—New)**

The draft guidance suggests that applicants who submit certain medical device applications include, if readily available, pediatric use information for diseases or conditions that the device is being used to treat, diagnose, or cure that are outside the device's approved or proposed indications for use, as well as an estimate of the number of pediatric patients with such diseases or conditions. The information submitted will allow FDA to identify pediatric uses of devices outside their approved or proposed indication for use in order to determine areas where further pediatric device development could be useful. This recommendation applies to applicants who submit the following applications:

1. Any request for a humanitarian device exemption submitted under section 520(m) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(m));

2. Any premarket approval application (PMA) or supplement to a PMA submitted under section 515 of the FD&C Act (21 U.S.C. 360e);

3. Any product development protocol submitted under section 515 of the FD&C Act.

In the **Federal Register** of February 19, 2013, (78 FR 11654), FDA published a 60-day notice requesting public comment on the proposed collection of information. However, only one comment was interpreted as being related to the proposed collection of information.

One comment stated that FDA should not require all readily available information on pediatric uses of devices because it is unduly burdensome, but rather applicants should be required to perform a reasonable search. FDA disagrees with the comment. In order for FDA to be provided useful, comprehensive information and to fulfill the statutory mandate, all readily available information should be submitted to FDA. Moreover, the requirement is not unduly burdensome because FDA is only requiring all information that is readily available, not all information in general.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Description | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Uses outside approved indication | 148 | 1 | 148 | 0.5 | 74 |

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

Respondents are permitted to submit information relating to uses of the device outside the approved or proposed indication if such uses are described or acknowledged in acceptable sources of readily available information. We estimate that 20 percent of respondents submitting information required by section 515A of the FD&C Act will choose to submit this information and that it will take 30 minutes for them to do so.

This draft guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in part 814 (21 CFR part 814), subpart B have been approved under OMB control number 0910–0231, and the collections of information in part 814, subpart H have been approved under OMB control number 0910–0332.

Dated: December 11, 2013.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2013–29796 Filed 12–13–13; 8:45 am]

**BILLING CODE 4160–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.