regulations and policies for this program. It provides guidance, review, support and assistance to states and grantees on HHS policies, regulations, procedures and systems necessary to assure efficient program operation at the state, territorial and tribal levels.

The Division of CSBG is responsible for assessing compliance with the provisions reviewing and resolving formal complaints, reviewing and recommending approval or disapproval of waiver requests, and evaluating activities in the programs, as appropriate.

D. Division of Community Discretionary and Demonstration Programs administers a variety of discretionary grant programs that foster family stability, economic security, responsibility and self-support, and promote and provide services to low-income individuals. These programs are administered either through grants, contracts or jointly financed cooperative arrangements. Assistance may be provided to states, public and private non-profit organizations and community agencies to provide technical assistance, training and on-going services and activities of national, regional or state-wide significance. Assistance may also be provided to private, locally-initiated, non-profit community development corporations (or affiliates of such corporations). This assistance may be provided to address a variety of areas of interest, such as rural housing and community facilities, assistance to migrants and seasonal farm workers, recreational and educational activities for low-income youth, community food and nutrition, support programs for homeless individuals, job creation, and business development opportunities. The Division also administers continued-use-of-assets agreements between OCS and Community Development Corporations (CDCs).

This division also administers demonstration programs that develop new and innovative approaches to deal with the critical needs of the poor which are common to many communities, reduce welfare dependency, and create business and employment opportunities. These programs, including the Assets for Independence (AFI) program, are administered either through grants, contracts or jointly financed cooperative arrangements. In coordination with the Office of Planning, Research and Evaluation (OPRE), the Division oversees and monitors demonstration programs; evaluates projects for their effectiveness in order to replicate those which are most successful; and prepares reports on significant findings.

E. Division of Social Services administers the Social Services Block Grant (SSBG). It is responsible for developing, updating and implementing regulations and policies for this program. It provides guidance, review, support and assistance to states and grantees on HHS policies, regulations, procedures and systems necessary to assure efficient program operation at the state, territorial and tribal levels. The Division of Social Services is responsible for administering emergency supplemental disaster funding assessing compliance with the provisions of the SSBG program, reviewing and resolving formal complaints, reviewing and recommending approval or disapproval of waiver requests, and evaluating activities in the programs, as appropriate.

II. *Continuation of Policy.* Except as inconsistent with this reorganization, all statements of policy and interpretations with respect to organizational components affected by this notice within ACF, heretofore issued and in effect on this date of this reorganization are continued in full force and effect.

III. *Delegation of Authority.* All delegations and re-delegations of authority made to officials and employees of affected organizational components will continue in them or their successors pending further re-delegations, provided they are consistent with this reorganization.

IV. *Funds, Personnel, and Equipment.* Transfer of organizations and functions affected by this reorganization shall be accompanied in each instance by direct and support funds, positions, personnel, records, equipment, supplies, and other resources.

This reorganization will be effective upon date of signature.

Dated: August 19, 2016.

Mark H. Greenberg,

Acting Assistant Secretary for Children and Families.

[FR Doc. 2016–20400 Filed 8–24–16; 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

TITLE: Assessing the Implementation and Cost of High Quality Early Care and Education: Comparative Multi-Case Study.

OMB NO.: New.

DESCRIPTION: The Administration for Children and Families (ACF) at the U.S. Department of Health and Human Services (HHS) seeks approval to collect new information to use in developing measures of the implementation and costs of high quality early care and education. This information collection is part of the project, Assessing the Implementation and Cost of High Quality Early Care and Education (ECE–ICHQ). The project's goal is to create a technically sound and feasible instrument that will provide consistent, systematic measures of the implementation and costs of education and care in center-based settings that serve children from birth to age 5. The resulting measures will inform research, policy, and practice by improving understanding of variations in what centers do to support quality, their associated costs, and how resources for ECE may be better aligned with expectations for quality.

The goals of the study are (1) to test and refine a mixed methods approach to identifying the implementation activities and costs of key functions within ECE centers and (2) to produce data for creating measures of implementation and costs. The study is currently collecting data through on-site visits to 24 centers as part of an initial phase of data collection under clearance, #0970–0355. This initial phase is meant to test data collection tools and methods, conduct cognitive interviewing to obtain feedback from respondents about the tools, and reduce and refine the tools for the next phase of data collection.

This request is focused on the next phase of data collection which will include 72 ECE centers in three states. The next phase will rely on remote data collection through electronic data collection tools, telephone interviews, and web-based surveys.

RESPONDENTS: ECE site administrators or center directors, program directors, education specialists, financial managers or accountants, teachers, and aides.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Center recruitment call screener (to confirm selection criteria and gain participation; assumes outreach to 5 centers for every 1 center needed)	360	1	.33	119
Center engagement call script (to gather basic characteristics and plan steps for participation)	72	1	.75	54
Implementation interview protocol	72	1	8	576
Electronic cost workbook	72	1	6	432
Cost interview protocol	72	1	2	144
Web-based time-use survey	579	1	.5	290

Estimated Total Annual Burden Hours: 1,615 hours.

ADDITIONAL INFORMATION: 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 Planning, Research and Evaluation, 330 C Street SW., 4th Floor, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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,

ACF Reports Clearance Officer.

[FR Doc. 2016–20386 Filed 8–24–16; 8:45 am]

BILLING CODE 4184–23–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–1292]

Abbreviated New Drug Application Submissions—Refuse To Receive for Lack of Justification of Impurity Limits; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a guidance for industry entitled ''Abbreviated New Drug Application Submissions—Refuse to Receive for Lack of Justification of Impurity Limits.'' This guidance is intended to assist applicants preparing to submit to FDA abbreviated new drug applications (ANDAs) and prior approval supplements for which the applicant is seeking approval of a new strength of the drug product. The guidance highlights deficiencies about impurity information that may cause FDA to refuse to receive (RTR) an ANDA.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2014–D–1292 for ''Abbreviated New Drug Application Submissions—Refuse to Receive for Lack of Justification of Impurity Limits.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the