

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.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov*. Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research, and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: OPRE Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The proposed data collection will be used by the Office of Child Care (OCC) to monitor State CCDF Lead Agencies to determine and validate compliance with CCDF regulations and the approved State Plan. The data collection is designed to provide States with the flexibility to propose an approach that is feasible and sufficient to demonstrate compliance based on State circumstances and processes. State Lead Agencies will participate in onsite monitoring based on a 3-year cohort; submitting data once every three years. OCC will begin monitoring for compliance in Fiscal Year 2019.

The data collection for the first 3-years will focus on 11 topical areas: (1)

Disaster Preparedness, Response and Recovery; (2) Consumer Education: Dissemination of Information to Parents, Providers, and General Public (Monitoring Reports and Annual Aggregate Data); (3) Twelve-Month Eligibility; (4) Child: Staff Ratios and Group Sizes; (5) Health and Safety Requirements for Providers (11 Health and Safety Topics); (6) Pre-Service/Orientation and Ongoing Training Requirements for Providers; (7) Inspections for CCDF Licensed Providers; (8) Inspections for License-Exempt CCDF Providers; (9) Ratios for Licensing Inspectors; (10) Child Abuse and Neglect Reporting; and (11) Program Integrity.

In developing the Onsite Monitoring System, OCC convened a workgroup of states to provide feedback and input on the design of the Onsite Monitoring System. As part of the workgroup discussions, states emphasized the need for individualized monitoring because of the complexity of each state's CCDF structure and variance in implementation strategies. As a response, OCC developed the Compliance Demonstration Packet that offers states the opportunity to propose their approach to demonstrating compliance based on how their CCDF program is administered. OCC also consulted other federal programs and monitoring experts on the Onsite Monitoring System's development and

incorporated their feedback regarding the efficiency and efficacy of the proposed process.

During the development of the Onsite Monitoring System, OCC conducted pilots in a number of States. Feedback received from pilot States and the pilot results were used to enhance the monitoring process and data collection method. Burden estimates below are based on an analysis of data collected through all of the pilot visits while accounting for variance in state documentation.

Respondents: State grantees and the District of Columbia.

Annual Burden Estimates: Respondents will be required to submit 2 separate instruments. First the Compliance Demonstration Chart will be submitted and reviewed by ACF-OCC. For this chart, OCC is looking for a high-level description of how the state proposes to demonstrate compliance. No additional materials should be submitted with this chart. After review by OCC, any changes or edits to the chart will be finalized in collaboration with the State. Once the final Compliance Demonstration Chart is submitted, the State will have 4–6 weeks to complete the Document Submission Chart and provide the associated materials.

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Compliance Demonstration Chart	17	1	16	272
Document Submission Chart	17	1	80	1,360

Estimated Total Annual Burden Hours: 1,632.

Authority: Sec. 658I of the Child Care and Development Block Grant Act Subpart J of 45 CFR, Part 98 of the Child Care and Development Fund.

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

[OMB No. 0970-0416]

Submission for OMB Review; Comment Request

Title: 2020 Current Population Survey-Child Support Supplement.

Description: Collection of these data will assist legislators and policymakers

in determining how effective their policymaking efforts have been over time in applying the various child support legislation to the overall child support enforcement picture. This information will help policymakers determine to what extent individuals on welfare would be removed from the welfare rolls as a result of more stringent child support enforcement efforts.

Respondents: Individuals and households.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
2020 Current Population Survey-Child Support Supplement	41,300	1	0.03	1,239

Estimated Total Annual Burden Hours: 1,239.

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, 330 C Street SW, Washington, DC 20201. Attention 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.

Mary B. Jones,
ACF/OPRE Certifying Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Statement of Organization, Functions, and Delegations of Authority

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of the Commissioner, Headquarters organizations, and Centers have modified their structures.

FOR FURTHER INFORMATION CONTACT: William Tootle, Director, Office of Budget, Office of the Commissioner, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 72094, Beltsville, MD 20705-4304, 301-796-4710.

SUPPLEMENTARY INFORMATION:

I. Introduction

Part D, Chapter D-B, (Food and Drug Administration), the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970; 60 FR 56606, November 9, 1995; 64 FR 36361, July 6, 1999; 72 FR 50112, August 30, 2007; 74 FR 41713, August

18, 2009; and 76 FR 45270, July 28, 2011) is amended to reflect the reorganization of the Office of the Commissioner/FDA Headquarters and the following Centers: Center for Devices and Radiological Health (CDRH), Center for Drug Evaluation and Research (CDER), Center for Food Safety and Applied Nutrition (CFSAN), Center for Tobacco Products (CTP), and Center for Veterinary Medicine (CVM).

The Office of the Commissioner reorganization will transition FDA away from the Directorate structure. Abolishing the current directorate structure and realigning many of those functions to the Centers/Office of Regulatory Affairs (ORA) establishes a direct line of communication between the Centers/ORA and the Commissioner of Food and Drugs. This direct report relationship with the Centers streamlines communications and better positions FDA to support its regulatory programs and mission. The intent is to create a more effective structure that better reflects FDA's priorities and streamlines operations.

The CDRH reorganization will more accurately reflect the functions performed by the Center and help to enhance CDRH's ability to advance FDA's mission and streamline operations and support functions.

The CDER reorganization changes the organizational structures and revises the functional statements of following organizations: Office of Communication (OCOMM), Office of Compliance (OC), Office of Executive Programs (OEP), Office of Hematology and Oncology Products (OHOP), and Office of New Drugs (OND). The proposed organizational changes will enhance CDER's ability to develop, coordinate, and evaluate public health communication and education activities in support of the following:

The CDER Office of Compliance proposed structure change will establish the framework for a stronger regulatory oversight of the compounded human drugs facilities and compounding related activities. The new structure will help ensure the following: That compounding pharmacies operate within the bounds of traditional pharmacy practice (not manufacturing); that outsourcing facilities operate according to the conditions in section 503B; and the new structure will protect patients from unsafe or ineffective compounded drugs.

The CDER Office of Communication is planning to expand CDER's communications outreach and educational efforts to inform the conversation among FDA's stakeholders. This will be managed through accessing

more communication channels, enhancing FDA's social media presence, and using more innovative tools. The impact of CDER's growth has impacted the volume of information posted on the web as the content management and development of tools used to connect stakeholders with web content are created. As new programs and initiatives are developed by the Center, the web content will increase. The new content management system will provide the Agency with the opportunity to finally have a true publishing tool. This will allow greater speed in posting the content in the web environment.

The CDER Office of Executive Programs houses all the executive functions for CDER and ensures the goals and priorities of the Center Director are carried out. These functions range from administrative support for the Center Director's Office, overseeing the Center's learning and organizational development program, to managing the Center's 18 different Advisory Committees. Restructuring these functions into defined organizational structures will improve decision making by promoting the direct flow of information from frontline employees to the managers directly responsible for making decisions and provide clarity to staff roles and responsibilities.

Furthermore, the proposed organizational changes permit Office of Executive Programs' managers to better define critical business processes and identify opportunities for streamlining complex tasks, which will facilitate a more efficient and strategic deployment of these resources during public health emergencies and outbreaks. The proposed changes align with Reimagine HHS guiding principle #3—Generating Efficiencies through Streamlined Processes and Reimagine HHS guiding principle #5—HHS as a More Innovative and Responsive Organization.

The CDER Office of Hematology and Oncology Products reorganization is in response to Title III of the 21st Century Cures Act (Cures Act), enacted into law on December 13, 2016, which provides authorities FDA can use to help modernize drug, biological, and device product development and review to create greater efficiencies and predictability in product development and review. Numerous initiatives are currently taking place in the Agency to carry out the plan laid out in the Cures Act and include: Patient Focused Drug Development; Novel Clinical Trial Design; Real World Evidence; Summary-level Review and Inter-Center Institutes; as well as other initiatives. The Office of Hematology and Oncology Products