

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

*Title:* Child Care and Development Fund, Annual Aggregate Report (ACF-800).

*OMB No.:* 0970-0150.

*Description:* Section 658K of the Child Care and Development Block Grant (CCDBG) Act (42 U.S.C. 9858, as amended by Pub. L. 113-186) requires that States and Territories submit annual aggregate data on the children and families receiving direct services under the Child Care and Development Fund (CCDF). The implementing regulations for the statutorily required reporting are at 45 CFR 98.70 and 98.71. Annual aggregate reports include data elements represented in the ACF-800 reflecting the scope, type, and methods

of child care delivery. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF-800 without changes.

*Respondents:* States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Mariana Islands.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF-800 .....	56	1	42	2,352

*Estimated Total Annual Burden Hours:* 2,352.

In compliance with the requirements of the Paperwork Reduction Act of 1995 (Pub. L. 104-13, 44 U.S.C. Chap 35), 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, Washington, DC 20201. Attn: ACF Reports Clearance Officer. Email address: [infocollection@acf.hhs.gov](mailto: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. 2018-09384 Filed 5-2-18; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2017-D-5913]

**Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017; 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 final guidance for industry entitled "Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017." This guidance concerns FDA's implementation of the Prescription Drug User Fee Amendments of 2017 (PDUFA VI) and certain changes in policies and procedures surrounding its application.

**DATES:** The announcement of the guidance is published in the **Federal Register** on May 3, 2018.

**ADDRESSES:** You may submit either electronic or written comments on Agency guidances at any time as follows:

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, 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-2017-D-5913 for "Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send

one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Peter Chen, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, Rm. 2112, Silver Spring, MD 20993, 240–402–8605, [Peter.Chen@fda.hhs.gov](mailto:Peter.Chen@fda.hhs.gov); or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a guidance for industry entitled “Assessing User Fees Under the Prescription Drug User Fee Amendments of 2017.” This guidance concerns the implementation of the PDUFA VI and certain changes in policies and procedures surrounding its application. Because PDUFA VI created significant changes to the user fee program, this guidance serves to provide an explanation about the new fee structure and types of fees for which applicants are responsible.

PDUFA VI provides two different fee types that applicants pay: Application and program fees. This guidance describes when these fees are incurred and the process by which applicants can submit payments. The guidance also provides information on consequences of failing to pay PDUFA VI fees as well as the process for submitting a reconsideration and appeals request.

In the **Federal Register** of October 13, 2017 (82 FR 47748), FDA announced the availability of a draft version of this guidance and provided interested parties an opportunity to submit comments. We have reviewed the comments submitted to the docket and determined that they did not raise any relevant issues. This guidance does not include any substantive changes from the draft guidance.

This guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on assessing user fees under PDUFA VI. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

**II. Electronic Access**

Persons with access to the internet may obtain the guidance at either <https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <https://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, or <https://www.regulations.gov>.

Dated: April 24, 2018.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2018–09366 Filed 5–2–18; 8:45 am]

**BILLING CODE 4164–01–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Meeting of the Pain Management Best Practices Inter-Agency Task Force**

**AGENCY:** Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** As stipulated by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that a meeting is scheduled to be held for the Pain Management Best Practices Inter-Agency Task Force (Task Force). The meeting will be open to the public; public comment sessions will be held during the meeting.

**DATES:** The inaugural meeting will be held on Wednesday, May 30, 2018, from 9:30 a.m. to 5:00 p.m. Eastern Time and Thursday, May 31, 2018, from 9:00 a.m. to 3:30 p.m. Eastern Time. The agenda will be posted on the Task Force website at <https://www.hhs.gov/ash/advisory-committees/pain/index.html>.

**ADDRESSES:** U.S. Department of Health and Human Services, Hubert H. Humphrey Building, Great Hall, 200 Independence Avenue SW, Washington, DC 20201.

**FOR FURTHER INFORMATION CONTACT:** Alicia Richmond Scott, Designated Federal Officer, Pain Management Best Practices Inter-Agency Task Force, U.S. Department of Health and Human Services, Office of the Assistant Secretary for Health, 200 Independence Avenue SW, Room 736E, Washington, DC 20201. Email: [paintaskforce@hhs.gov](mailto:paintaskforce@hhs.gov).

**SUPPLEMENTARY INFORMATION:** Section 101 of the Comprehensive Addiction and Recovery Act of 2016 (CARA) authorizes the Secretary of Health and Human Services, in cooperation with