

ANNUAL BURDEN ESTIMATES

| Instrument                        | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|-----------------------------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Application & Annual Report ..... | 52                    | 1                                  | 60                                | 3,120              |

Estimated Total Annual Burden Hours: 3,120

**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, Fax: 202-395-7285, Email: *OIRA\_SUBMISSION@OMB.EOP.GOV*, Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2014-04094 Filed 2-25-14; 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:* Child Support Enforcement Program Expenditure Report (Form

OCSE-396) and the Child Support Enforcement Program Collection Report (Form OCSE-34).

*OMB No.:* 0970-0181.

*Description:* State and Tribal agencies administering the Child Support Enforcement Program under Title IV-D of the Social Security Act are required to provide information each fiscal quarter to the Office of Child Support Enforcement (OCSE) concerning administrative expenditures and the receipt and disposition of child support payments from non-custodial parents. State title IV-D agencies report quarterly expenditures and collections using Forms OCSE-396 and OCSE-34, respectively. Tribal title IV-D agencies report quarterly expenditures using Form SF-425, as prescribed in program regulations, and formerly reported quarterly collections using only a modified version of Form OCSE-34. The information collected on these reporting forms is used to compute quarterly grant awards to States, the annual incentive payments to States, and provides valuable information on program finances of States and Tribes. The collected information is also included in a published annual statistical and financial report, available to the general public.

In response to an earlier **Federal Register** Notice (77 FR 72352 December, 2012), this agency received comments to support the minor changes and revisions to these forms at this time. As we continued to discuss improvements to these reporting forms with State and Tribal grantees we list a few minor revisions that have been incorporated to facilitate grant award operations and grantee financial reporting. These revisions were limited to any changes that allow Tribal grantees to, at least, use the same quarterly collection report submitted by State grantees. Additionally, further clarification was provided to reduce confusion over the

inclusion of the Federal share of funding in computations of claims and to standardize treatment of claims. Finally, there were minor revisions in the title of the forms by reverting to the original designation as Form OCSE-396 and Form OCSE-34 and minor changes to the existing wording to improve clarity and accuracy.

One respondent was concerned with the Tribal and State governments using the same OCSE-34 Form, which was perceived to lead to an added burden and confusion about the submission of specific data elements. Our sense is that the form is developed in a sufficiently clear manner to inform respondents on the data elements required by each type of grantee. Furthermore, we consistently provide outreach and technical assistance to all grantees to ensure that reporting burdens are clear and minimized.

A few respondents provided technical and clerical edits to the OCSE-396 Form to increase accuracy and clarity. We have incorporated many of the requested edits and appreciate the detailed and thoughtful comments.

One respondent was concerned that the instructions to the OCSE-396 may be creating an additional burden by maintaining a 5 percent variance threshold (an increase or decrease in any data element of Part 1 compared to that same data element for the previous quarter). While we are understanding of this concern our position is that the form will be used nationally and raising the variance threshold above 5 percent is not justified at this time.

*Respondents:* State and Tribal agencies (including New York, Texas, Washington, Puyallup Tribe, and Port Gamble S'Klallam Tribe) administering a Child Support Enforcement Program.

ANNUAL BURDEN ESTIMATES

| Instrument     | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|----------------|-----------------------|------------------------------------|-----------------------------------|--------------------|
| OCSE-396 ..... | 54                    | 4                                  | 6                                 | 1,296              |
| OCSE-34 .....  | 114                   | 4                                  | 14                                | 6,384              |

Estimated Total Annual Burden Hours: 7,680.

**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](mailto: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, Fax: 202-395-7285, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

[FR Doc. 2014-04192 Filed 2-25-14; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-0001]

#### Advisory Committees; Filing of Closed Meeting Reports

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the Agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2013.

**ADDRESSES:** Copies are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 301-827-6860.

#### FOR FURTHER INFORMATION CONTACT:

Teresa L. Hays, Committee Management Officer, Advisory Committee and Oversight Management Staff, Food and Drug Administration, 10903 New

Hampshire Ave., Silver Spring, MD 20993-0002, 301-796-8220.

**SUPPLEMENTARY INFORMATION:** Under section 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2012, through September 30, 2013:

#### *Center for Biologics Evaluation and Research*

Blood Products Advisory Committee, Cellular, Tissue, and Gene Therapies Advisory Committee, Vaccines and Related Biological Products Advisory Committee.

#### *National Center for Toxicological Research*

Science Board to the National Center for Toxicological Research.

#### *Center for Tobacco Products*

Tobacco Products Scientific Advisory Committee.

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

- (1) The Library of Congress, 101 Independence Ave. SE., James Madison Memorial Bldg., Newspaper and Current Periodical Reading Room, Rm. 133, Washington, DC 20540; and
- (2) The Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 21, 2014.

**Jill Hartzler Warner,**

*Acting Associate Commissioner for Special Medical Programs.*

[FR Doc. 2014-04144 Filed 2-25-14; 8:45 am]

**BILLING CODE 4160-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2013-D-0811]

#### Guidance for Industry: Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation To Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is

announcing the availability of a draft guidance for industry entitled “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,” dated March 2014. This draft guidance informs members of the medical and scientific community and other interested persons that we intend to exercise enforcement discretion regarding the investigational new drug (IND) requirements for the use of fecal microbiota for transplantation (FMT) to treat *C. difficile* infection not responding to standard therapies, provided the licensed health care provider treating the patient obtains adequate informed consent from the patient or his or her legally authorized representative for use of the FMT products, the stool is obtained from a donor known to either the patient or the licensed health care provider treating the patient, and the donor and stool are qualified by screening and testing performed under the direction of the licensed health care provider for the purpose of providing the FMT product to treat his or her patient. This draft guidance, when finalized, is intended to supersede the guidance document entitled “Enforcement Policy Regarding Investigational New Drug Requirements for Use of Fecal Microbiota for Transplantation to Treat *Clostridium difficile* Infection Not Responsive to Standard Therapies,” dated July 2013 (July 2013 Guidance).

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by March 28, 2014.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Office of Communication, Outreach and Development (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written