ANNUAL BURDEN ESTIMATES—Continued

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Annex A: Status of Application Report	54	37	.33	659
Annex B: Application for Enforcement of a Decision Made or Recognized in the Requested State, including restricted information on the applicant	54	19	.5	513
Annex B: Status of Application Report, Article 12	54	37	.33	659
Annex C: Application for Establishment of a Decision, including restricted information on the Applicant	54	5	.5	135
Annex C: Status of Application Report—Article 12	54	9	.33	160
Annex D: Application for Modification of a Decision, including Restricted Information on the Applicant	54	5	.5	135
Annex D: Status of Application Report—Article 12	54	9	.33	160
Annex E: Financial Circumstances Form	54	46	2	4,968

Estimated Total Annual Burden Hours: 13,478.

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.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–29590 Filed 12–8–16; 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 Proposed Projects:

Title: ADP & Services Conditions for FFP for ACF.

OMB No.: 0970–0417.

Description: State child support agencies are required to establish and operate a federally approved statewide automated data processing and information retrieval system to assist in child support enforcement. States are required to submit an initial advance automated data processing planning document (APD) containing information to assist the Secretary of the Department of Health and Human Services in determining if the state computerized support enforcement system meets federal requirements and providing federal approval. States are also required to submit annually an updated APD for oversight purposes. Based on assessment of the information provided in the initial or updated APDs, states that do not meet federal requirement approval will need to complete an independent verification and validation.

The Advance Planning Document (APD) process, established in the rules at 45 CFR part 95, Subpart F, is the procedure by which States request and obtain approval for Federal financial participation in their cost of acquiring Automatic Data Processing (ADP) equipment and services. State agencies that submit APD requests provide the Department of Health and Human Services (HHS) with the following information necessary to determine the States' needs to acquire the requested ADP equipment and/or services:

Respondents: States.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
RFP and Contract	54	1.5	4	324
Emergency Funding Request	5	.1	2	1
Biennial Reports	54	1	1.50	81
Advance Planning Document	34	1.2	120	4,896
Operational Advance Planning Document	20	1	30	600
Independent Verification and Validation (ongoing)	3	4	10	120
Independent Verification and Validation (semiannually)	1	2	16	32
Independent Verification and Validation (quarterly)	1	4	30	120
System Certification	1	1	240	240

Estimated Total Annual Burden Hours: 6,414.

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.* 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. 2016–29583 Filed 12–8–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–4096]

Final Assessment of the Program for Enhanced Review Transparency and Communication; Public Meeting and Establishment of Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting and establishment of docket, request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of a docket to obtain comments on the final assessment of the Program for Enhanced Review Transparency and Communication for New Molecular Entity (NME) New Drug Applications (NDAs) and Original Biologics License Applications (BLAs) (the Program). FDA is also announcing a public meeting where the final assessment will be discussed and public stakeholders may present their views on the Program to date. The Program is part of the FDA performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA), which enables FDA to collect user fees for the review of human drug and biologics applications for fiscal years (FYs) 2013–2017. The Program is described in detail in section II.B of the document entitled ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017.'' The Program is being evaluated by an independent contractor with expertise in assessing the quality and efficiency of pharmaceutical and biopharmaceutical development and regulatory review programs. As part of FDA's performance commitments, FDA is providing a period for public comment on the final assessment of the Program.

DATES: The public meeting will be held on March 27, 2017, from 10 a.m. to 1 p.m. Public comments will be accepted through April 3, 2017. See the **ADDRESSES** section for information about submitting comments to the public docket. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 2, Conference Room 2047 E, Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

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–2016–N–4096. 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 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 *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. 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: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*