

portal; to manually enter data within the web portal itself; or to submit .xml files containing their information. Once the states and issuers submit their data, they will receive an email notifying them of any errors, and that their submission was received.

CMS is mandating the issuers verify and update their information on a quarterly basis and is requesting that States verify State-submitted information on an annual basis. In the event that an issuer enhances its existing plans, proposes new plans, or deactivates plans, the organization would be required to update the information in the web portal. Changes occurring during the three month quarterly periods will be allowed utilizing effective dates for both the plans and rates associated with the plans.

Form Number: CMS-10320 (OMB#: 0938-1086); *Frequency:* Reporting—Annually/Quarterly; *Affected Public:* health insurance issuers in the individual and small group markets; *Number of Respondents:* 801; *Total Annual Responses:* 3,051; *Total Annual Hours:* 27,833. (For policy questions regarding this collection contact Kim Heckstall at 410 786 1647.)

Dated: January 28, 2014.

Martique Jones,

Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

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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:

- (1) A statement of need;
- (2) A requirements analysis and feasibility study;
- (3) A procurement plan;
- (4) A proposed activity schedule; and,
- (5) A proposed budget.

The proposed information collection, is authorized by (1) 42 U.S.C. 654A, which provides a state agency to have a single statewide automated data processing and information retrieval system and sets forth the requirements of that system; (2) 42 U.S.C. 654(16), which provides the state must submit an initial, and annually updated, advance automated data processing planning document for project approval; (3) 45 CFR 307.15, which provides the requirements for approval of advance planning documents; (4) 42 U.S.C. 652(d), which provides the Secretary with the authority to approve an APD and to assess the computerized support enforcement system status; 45 CFR 95.626, which determines when an Independent Verification and Validation must be completed.

HHS' determination of a State Agency's need to acquire requested ADP equipment or services is authorized at sections 602(a(5)), 652(a)(1), 1396(a)(4) and 1302 of United States Code.

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	4	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 Section 506(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, 370 L'Enfant Promenade SW., Washington, DC 20447. 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.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0078]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug User Fee Act Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork burden of animal drug sponsors to fill out the Animal Drug User Fee Act (ADUFA) cover sheet.

DATES: Submit either electronic or written comments on the collection of information by April 4, 2014.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical

utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Animal Drug User Fee Cover Sheet—(OMB Control Number 0910-0539)—Extension

Under section 740 of the FD&C Act (21 U.S.C. 379j-12), as amended by ADUFA (Pub. L. 108-130), FDA has the authority to assess and collect for certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The ADUFA cover sheet (Form FDA 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FD&C Act section amended by ADUFA	FDA Form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(a)(1)	3546 (Cover Sheet)	17	1 time for each application.	17	1	17

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's database system, there are an estimated 173 manufacturers of products or sponsors of new animal

drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the

average number of submissions received by FDA in fiscal years 2011-13. The estimated hours per response are based on past FDA experience with the various submissions. The hours per