

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7-1044, One Choke Cherry Road, Rockville, MD 20857 and e-mail her a copy at [summer.king@samhsa.hhs.gov](mailto:summer.king@samhsa.hhs.gov). Written comments should be received within 60 days of this notice.

Dated: April 1, 2009.

**Elaine Parry,**

Director, Office of Program Services.

[FR Doc. E9-7779 Filed 4-6-09; 8:45 am]

**BILLING CODE 4162-20-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Submission for OMB Review; Comment Request**

*Title:* Building Strong Families (BSF) Demonstration and Evaluation Impact Study Second Follow-up.

*OMB No.:* 0970-0304.

*Description:* The Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), anticipates continuing data collection for the 15-month follow-up surveys of the Building Strong Families (BSF) Demonstration and Evaluation. Data collection will continue for an additional 6 months beyond the current date of expiration (July 31, 2009).

This data collection is a part of the BSF evaluation, which is an important opportunity to learn if well-designed interventions can help low-income couples develop the knowledge and relationship skills that research has shown are associated with healthy marriages. The BSF evaluation uses an experimental design that randomly assigns couples who volunteer to participate in BSF programs to a program or control group.

Materials for the original 15-month data collection effort, previously submitted to OMB, covered impact and implementation data collections. Data collection for the impact study is complete. ACF anticipates collecting data for an additional 6 months in order to complete data collection for the entire sample of participants.

*Respondents:* Couples enrolled in the BSF evaluation, including program and control groups.

**ANNUAL BURDEN ESTIMATES**

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
15-month telephone survey (female partner) .....	1,434	1	.91	1,305
15-month telephone survey (male partner) .....	1,434	1	.83	1,190

*Total Burden Hours:* 2,495.

*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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@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: 202-395-6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 30, 2009.

**Brendan C. Kelly,**

OPRE Reports Clearance Officer.

[FR Doc. E9-7501 Filed 4-6-09; 8:45 am]

**BILLING CODE 4184-01-M**

*Title:* Head Start Grant Application and Budget Instruments.

*OMB No.:* 0970-0207.

*Description:* The Office of Head Start is proposing to renew, without changes, the Head Start Grant Application and Budget Instrument, which standardizes the grant application information that is requested from all Head Start and Early Head Start grantees applying for continuation grants. The application and budget forms are available in a password-protected, Web-based system. Completed applications can be transmitted electronically to Regional and Central Offices. The Administration for Children and Families believes that this application form makes the process of applying for Head Start program grants more efficient for applicants.

*Respondents:* Head Start and Early Head Start grantees.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
HS grant and budget instrument .....	1,600	1	33	52,800
<i>Estimated Total Annual Burden Hours:</i> .....	.....	.....	.....	52,800

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 can be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail 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.

Dated: April 1, 2009.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E9-7705 Filed 4-6-09; 8:45 am]

BILLING CODE 4184-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2009-N-0148]

#### Generic New Animal Drug User Fee Rates and Payment Procedures for Fiscal Year 2009

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the rates and payment procedures for fiscal year (FY) 2009 generic new animal drug user fees. The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Generic Drug User Fee Act of 2008 (AGDUFA), authorizes FDA to collect user fees for certain abbreviated

applications for a generic new animal drug, on certain generic new animal drug products, and on certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. This notice establishes the fee rates for FY 2009.

For FY 2009, the generic new animal drug user fee rates are: \$41,400 for each abbreviated application for a generic new animal drug; \$3,005 for each generic new animal drug product; \$56,350 for each generic new animal drug sponsor paying 100 percent of the sponsor fee; \$42,265 for each generic new animal drug sponsor paying 75 percent of the sponsor fee; and \$28,175 for a generic new animal drug sponsor paying 50 percent of the sponsor fee. AGDUFA required FDA to issue invoices for FY 2009 product and sponsor fees by December 31, 2008, or within 30 days of enactment of an appropriation for these fees, whichever is later. The appropriations were enacted on March 11, 2009. These fees will be due and payable within 30 days of the issuance of the invoices. The application fee rates are effective for all abbreviated applications for generic new animal drugs submitted on or after July 1, 2008, and will remain in effect through September 30, 2009.

**FOR FURTHER INFORMATION CONTACT:** Visit the FDA Web site at <http://www.fda.gov/oc/adufa/agdufamain.html> or contact Bryan Walsh, Center for Veterinary Medicine (HFV-10), Food and Drug Administration, 7529 Standish Pl., Rockville, MD 20855, 240-276-9730. For general questions, you may also e-mail the Center for Veterinary Medicine (CVM) at: [cvmagdufa@fda.hhs.gov](mailto:cvmagdufa@fda.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 741 of the act (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs, (2) annual fees for certain generic new animal drug products, and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). When certain conditions are met, FDA will waive or reduce fees for generic new animal drugs intended solely to provide for a minor use or minor species indication (21 U.S.C. 379j-21(d)).

For FY 2009 through FY 2013, the act establishes aggregate yearly base revenue amounts for each of these fee categories. Base revenue amounts established for years after FY 2009 are

subject to adjustment for workload. Fees for applications, products, and sponsors are to be established each year by FDA so that the revenue for each fee category will approximate the level established in the statute, after the level has been adjusted for workload.

##### II. Revenue Amount for FY 2009

###### A. Statutory Fee Revenue Amounts

AGDUFA (Title II of Public Law 110-316, signed by the President on August 14, 2008) specifies that the aggregate revenue amount for FY 2009 for abbreviated application fees is \$1,449,000 and the other two generic new animal drug user fee categories, annual product fees and annual sponsor fees, are \$1,691,000 each, before any adjustment for workload is made (see 21 U.S.C. 379j-21(b)).

###### B. Inflation Adjustment to Fee Revenue Amount

The amounts established in AGDUFA for each year for FY 2009 through FY 2013 include an inflation adjustment, so no further inflation adjustment is required.

###### C. Workload Adjustment Fee Revenue Amount

For each FY beginning after FY 2009, AGDUFA provides that statutory fee revenue amounts shall be further adjusted to reflect changes in review workload (21 U.S.C. 379j-21(c)(1)). No workload adjustment is to be made in fee revenue amounts for FY 2009.

##### III. Abbreviated Application Fee Calculations for FY 2009

The term "abbreviated application for a generic new animal drug" is defined in 21 U.S.C. 379j-21(k)(1).

###### A. Application Fee Revenues and Numbers of Fee-Paying Applications

The application fee must be paid for abbreviated applications for generic new animal drugs that are subject to fees under AGDUFA and that are submitted on or after July 1, 2008. The application fees are to be set so that they will generate \$1,449,000 in fee revenue for FY 2009. This is the amount set out in the statute and no adjustments to it are required for FY 2009.

To set fees for abbreviated applications for generic new animal drugs to realize \$1,449,000, FDA must first make some assumptions about the number of fee-paying abbreviated applications it will receive over the 15 months from July 1, 2008, through September 30, 2009.

The agency knows the number of such applications that have been submitted in previous years. That number