TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Section of the Act Types of Waiver or Reduction Requests	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
740(d)(1)(D) Minor use or minor species	10	"	10	2	20
740(d)(1)(E) Small business	2	"	2	2	4
Request for reconsideration of a decision	5	"	5	2	10
Request for review—(user fee appeal officer)	2	"	2	2	4
Total					60

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

Based on FDA's database system, there are an estimated 250 sponsors of products subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the number of submissions types received by FDA in fiscal year 2003. The Center for Veterinary Medicine estimates 30 waiver requests that include the following: 5 significant barriers to innovation, 1 fee exceed cost, 5 free choice feeds, 10 minor use or minor species, 2 small business waiver requests, 5 requests for reconsideration of a decision, and 2 requests for user fee appeal officers. The estimated hours per response are based on past FDA experience with the various waiver requests in the Center for Drug Evaluation and Research. The hours per response are based on the average of these estimates.

Dated: October 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–23104 Filed 10–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0185]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Cover Sheet

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 15, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance:

Animal Drug User Fee Cover Sheet; FDA Form 3547 (OMB Control Number 0910–0539)—Extension

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act (ADUFA) (21 U.S.C. 379j–12), FDA has the authority to assess and collect 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. Under the new statutory provisions (section 740(e) of the act, as amended by ADUFA), animal drug applications and supplemental animal drug applications for which the required fee has not been paid are considered incomplete and are not to be accepted for review by the agency. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet, FDA Form 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. Inability to collect this information would delay the review process and would also delay receipt of revenue that is to be used to fund the review of animal drug applications during the current fiscal year. Respondents to this collection of information are new animal drug applicants or manufacturers.

In the **Federal Register** of May 3, 2004 (69 FR 24168), FDA published a 60-day notice requesting comment on the collection of information. In response to that notice, no comments were received regarding the collection of information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act as Amended by ADUFA	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
740(a)(1) FDA Form 3547 (Cover Sheet)	69	1 time for each application	69	1	69

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

Based on FDA's database system, there are an estimated 140 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 number of submissions received by FDA in the fiscal year 2003. FDA's Center for Veterinary Medicine, estimates 69 annual responses that include the following: 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per response are based on past FDA experience with the various submissions and range from 30 minutes to 1 hour. The hours per response are based on the average of these estimates.

Dated: October 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–23105 Filed 10–13–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c) (2) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104–13), the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited 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) ways to enhance 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 of other forms of information technology.

Proposed Project: Survey of Safety Net Providers for the Healthy Communities Access Program National Evaluation—New

A survey of 800 safety net providers will be performed to provide essential information not otherwise available for the national evaluation of the Healthy Communities Access Program (Sect. 340, Pub. L. 107–251, Oct. 26, 2002). A preliminary review indicates that this sample of providers provides an adequate representation of provider types of most interest. The survey results will be considered along with information from other quantitative and qualitative data sources (including national, State and local data and information from grantee consortia leaders and clients) in order to develop a Report to Congress in September 2005 and a program evaluation report by September 2006. The survey will collect data for key evaluation goals including coordination and integration of safety net services, capacity and access issues, health care delivery, quality of care, cost savings, sustainability, and provider and patient satisfaction.

The survey of the provider institution's administrator will be multi-modal using mail, telephone, and internet modes of data collection. Mail or internet responses will be requested, with telephone follow-up or survey administration. The key types of providers to be surveyed are those specified in the law as required consortia members (*i.e.*, federally qualified health centers, hospitals, public health departments, and providers serving the medically uninsured and underserved). Two hundred providers of each type will be surveyed. The burden estimate is as follows:

Form	Number of respondents	Responses per respondent	Total reponses	Hours per response	Total burden hours
Survey	800	1	800	.33	264

Send comments to Susan G. Queen, Ph.D., HRSA Reports Clearance Officer, Room 14–33, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Written comments should be received with 60 days of this notice.

Dated: October 8, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04–23109 Filed 10–13–04; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds Announced in the HRSA Preview

AGENCY: Health Resources and Services Administration, HHS.