Based on FDA's experience, we expect it will take respondents this amount of time to obtain and draft the information to be submitted with a Pilot 2 application. Therefore, the agency estimates that applicants will use approximately 10,000 hours to complete the Pilot 2 applications.

On September 29, 2003, this guidance was approved on an emergency basis, which expires on March 30, 2004. This notice of request is to receive approval in the normal PRA process.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Pilot 2 Application	No. of Respondents	No. of Responses per Respondent	Total Responses	Hours per Response	Total Hours
CDER	85	1.06	90	80	7,200
CBER	29	1.20	35	80	2,800
Total					10,000

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

In the **Federal Register** of November 20, 2003, (68 FR 65457), FDA announced the availability of the guidance and requested comments for 60 days on the information collection. One comment was received that did not pertain to the information collection.

Dated: February 19, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4248 Filed 2–25–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0077]

Agency Emergency Processing Under Office of Management and Budget Review; 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 emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information, Animal Drug User Fee Cover Sheet (cover sheet), will be used 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. FDA is requesting this emergency processing under the PRA to implement new statutory requirements of the Animal Drug User Fee Act (ADUFA) (section 740(a)(1) of the Federal Food Drug and Cosmetic Act (the act). ADUFA requires FDA to collect fees from each person who submits certain new animal drug applications or supplements on or after September 1, 2003, and FDA may not accept applications for review if all fees have not been paid (section 740(e) of the act).

DATES: Fax written comments on the collection of information provisions by March 10, 2004. FDA is requesting approval of this emergency processing by March 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, or electronically mail comments to: *Fumie__Yokota@omb.eop.gov*. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). This information is needed immediately so that the agency can use the cover sheet to collect information from entities submitting animal drug applications. That information is needed to assure that the application fee payments are correctly associated with the payer of the fee and with the application for which payment is made.

ADUFA was signed into law on November 18, 2003 (Public Law 108–130) and the appropriation act enabling FDA to collect the newly authorized fees was signed into law on January 23, 2004 (Public Law 108–199). ADUFA requires FDA to collect animal drug application fees from each person who submits certain animal drug applications or supplements on or after September 1, 2003 (section 740(a)(1)(A) of the act). The use of normal clearance procedures would result in the prevention or disruption of this collection of information and the delay of fees that must be collected immediately to fund animal drug review activities in the current fiscal year. Therefore, FDA has requested approval of this emergency processing for this proposed collection of information by March 15, 2004.

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; FDA Form 3546

Under section 740 of the act, as amended by ADUFA (21 U.S.C. 379j-12), 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. 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 (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 he 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. FDA is requesting this emergency processing under the PRA to implement these new statutory requirements of ADUFA (section 740(a)(1) and (e) of the act). 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 3546 (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.

Respondents to this collection of information are new animal drug applicants or manufacturers. Based on FDA's data base 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 fiscal year 2003. The Center for Veterinary Medicine (CVM) 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: February 23, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–4309 Filed 2–23–04; 4:07 pm]

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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)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to 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 and draft instruments, 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 or other forms of information technology.

Proposed Project: Data Collection Tool for the Black Lung Clinics Program: In Use Without Approval

The Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA), conducts an annual data collection of user information for the Black Lung Clinics Program. The purpose of the Black Lung Clinics Program is to improve the health status of coal workers by providing services to minimize the effects of respiratory and pulmonary impairments of coal miners. Grantees provide specific diagnostic and treatment procedures required in the management of problems associated with black lung disease which improve the quality of life of the miner and reduces economic costs associated with morbidity and mortality arising from pulmonary diseases. The purpose of collecting this data is to provide HRSA with information on how well each grantee is meeting the needs of active and retired miners in the funded communities.

Data from the annual report will provide quantitative information about the programs, specifically: (a) The characteristics of the patients they serve (gender, age, disability level, occupation type), (b) the characteristics of services provided (medical, non-medical, or counseling), and (c) number of patients served and visits conducted (encounters). This assessment will provide data useful to the program and will enable HRSA to provide data required by Congress under the Government Performance and Results Act of 1993. It will also ensure that the organizations funded have demonstrated a need for services in their communities and that funds are being effectively used to provide services to meet those needs.

The estimated burden is a follows: