SUPPORTING STATEMENT
Animal Drug User Fees (ADUFA) Cover Sheet FDA Form 3546
OMB# 0910-0539

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

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. 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).

2. Purpose and Use of the Information

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 by FDA to track the payment. It will be used by FDA's Center for Veterinary Medicine and FDA's Office of Management to initiate the administrative screening of new animal drug applications and supplements to determine if payment has been received.

3. Use of Information Technology and Burden Reduction

The Center for Veterinary Medicine (CVM, the Center) is accepting electronic new animal drug applications in the near future.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requires this information. The required information is not available from any other source.

5. Impact on Small Businesses or Other Small Entities

FDA believes that its duty requires the equal application of the regulations to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses.

6. Consequences of Collecting the Information Less Frequently

If this information is not collected, the person subject to animal drug user fees would be required to have all fees, including the application fee paid prior to FDA accepting an application for filing.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for the collection of information requirements.

8. Consultations Outside FDA

In accordance with 5 CFR 1320.8(d), on June 15, 2007, in volume 72, No. 115, page 33231, a 60-day notice for public comment (Attachment 1) was published in the Federal Register. No comments were received from the public.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift was provided or will be provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and the agency's published regulations of "Public Information" under 21 CFR Part 20 which prohibit FDA from releasing to the public any information that cannot be disclosed. Such information is deleted from any information released by FDA under FOIA and FDA regulations.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection

12. Estimates of Hour Burden Including Annualized Hourly Costs

Table 1. -- Estimated Annual Reporting Burden[1]

FD&C Section 740(a)(1)	Number of Respondents	Annual Frequency per Response	Total annual Responses	Hours per Response	Total Hours
FDA Form 3546 Cover Sheet	69	1 time per application	69	1	69
Total					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. 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 one hour. The hours per response are based on the average of these estimates.

13. Estimated Annual Cost to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	60	$35	$2100

FDA estimates that the total annual cost to respondents will be $2100 in 2006 (60 hours X $35 per hour).

The cost to respondents is based on the salary of a regulatory affairs specialist, at a pay rate of $35 per hour, who is responsible for filling out, signing, and submitting the request. This salary estimate includes benefits but no overhead costs. There are no capital and start-up, or operation, maintenance and purchase costs associated with this information collection.

14. Estimated Annual Cost to Government

FDA estimates that it will spend about .50 FTEs annually on this information collection. We estimate about 1650 hours of work is performed per FTE. We estimate a compensation cost of $84,691 per FTE (Washington Metro Area pay scale), which is the salary of a GS13/3, the average grade among the personnel involved in the review. $84,691 times .50 = $42,346.

15. Changes in Burden

There is no change in burden from the 2004 collection of information data.

16. Publication of Results

Section 704(d)(3)(C) of the FD&C Act requires FDA to periodically publish in the Federal Register a list of persons making small business certifications. No other information will be published.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions.