SUPPORTING STATEMENT
Animal Generic Drug User Fees (AGDUFA)
Cover Sheet Form FDA 3728
OMB# 0910- XXXX

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Generic Drug User Fee Act of 2008 (AGDUFA) (Title II of Public Law 110-316 signed by the President on August 14, 2008), authorizes FDA to collect user fees for certain abbreviated applications for generic new animal drugs, 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.

2. Purpose and Use of the Information

The types of fees that require a cover sheet are certain abbreviated new animal drug applications. The cover sheet (Form FDA 3728) is designed to provide the minimum necessary information to determine whether a fee is required, to determine the amount of the fee required, and to assure that each generic animal drug user fee payment is made appropriately. 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 generic animal drug applications to determine if payment has been received.

3. Use of Information Technology and Burden Reduction

The Center for Veterinary Medicine (CVM, the Center) will accept electronic abbreviated 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 generic animal drug user fees would be required to have 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), a 60-day notice for public comment will published in the Federal Register following approval of this collection of information under the emergency processing provisions of the PRA of 1995.

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]

Form FDA #	Number of Respondents	Annual Frequency per Response	Total annual Responses	Hours per Response	Total Hours
3728	20	2	40	.08	3.2

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 generic animal drug applicants. Based on FDA's data base system, there are an estimated 20 sponsors of generic new animal drugs potentially subject to AGDUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. CVM estimates 40 annual responses.

13. Estimated Annual Cost to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	3.2	$35	$112

FDA estimates that the total annual cost to respondents will be $ (3.2 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.

16. Publication of Results

No 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.