SUPPORTING STATEMENT
Animal Generic Drug User Fees (AGDUFA)
Cover Sheet FDA Form 3728
OMB# 0910-0632

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Federal Food, Drug, and Cosmetic 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.

The Food and Drug Administration is submitting this revision in order to add a small number of changes to fields on its Form FDA 3728. 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), 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. 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 (CVM) and FDA's Office of Management to initiate the administrative screening of new generic animal drug applications to determine if payment has been received.

We do not expect a change in the hour or cost burden estimates due to these changes in the Form FDA 3728 because only a few fields (as described here below) will be added.

On Page 1 of the electronic questions under "Select an Application Type" users must select "Original" and then they choose one of the following:

- "Abbreviated New Animal Drug Application (ANADA) – under provisions of 512(b)(2) of FFDCA" or
- "Abbreviated New Animal Drug Application (ANADA) – for certain combination pioneer products approved under provisions of 512(d)(4) of FD &C Act"

If they select the second ANADA type, then they will be charged at rate of 50% of the original application fee. If they select the first, they will be charge 100% of the application fee.

On the resulting form itself (Form FDA 3728), we are adding another line in Section 3.

"3.2 Original Abbreviated New Animal Drug Application (ANADA) – for certain combination pioneer products approved under provisions of 512(d)(4) of the FD&C Act"

This information collection is not related to the American Recovery and Reinvestment Act of 2009.

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 (CVM) 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 Improved Information Technology and Burden Reduction

CVM 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 this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

For the instant revision FDA did not publish notice, however, the agency will publish a 60 day notice in accordance with 5 CFR 1320.8(d) incorporating the revisions discussed for this extension within the first quarter of 2014.

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 Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1. -- Estimated Annual Reporting Burden

FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total annual Responses	Average Burden per Response	Total Hours
FDA 3728; AGDUFA Cover Sheet	20	2	40	.08 (5 mins.)	3.2

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.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Regulatory Affairs Specialist	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.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeeping Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection

14. Annualized Cost to the 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 $94,969 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. $94,969 times .50 = $47,484.50.

15. Explanation for Program Changes or Adjustments

An adjustment in the estimate for the annual number of responses has been made

for the currently approval of 69. The new estimate for the annual number of responses being requested is 40. Respondents to this collection of information are generic drug applicants . Based on FDAs database systen, there are an estimated 20 sponsors of new animal drugs potentially subject to AGDUFA , with the number of responses per responses averaging around
2 , hence the total annual responses being 40.

16. Plans for Tabulation and Publication and Project Time Schedule

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 to the certification.