Animal Generic Drug User Fee (AGDUFA) Cover Sheet
OMB Control No. 0910-0632
Supporting Statement Part A

TERMS OF CLEARANCE: None

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Section 741 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-21) establishes three different kinds of user fees: (1) Fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). Because concurrent submission of user fees with applications is required, the review of an application cannot begin until the fee is submitted. Form FDA 3728 is the AGDUFA cover sheet, which is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

The Animal Generic Drug User Fee Amendments of 2013, signed by the President on June 13, 2013 (AGDUFA II) (Title II of Pub. L. 113-14), amended the FD&C Act authorizing FDA to collect user fees for certain abbreviated applications for generic new animal drugs, for certain generic new animal drug products, and for certain sponsors of such abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs. To implement changes under the reauthorization by their effective date of October 1, 2013, FDA sought and received OMB approval to update its Form FDA 3728 as described here:

On page 1 of the electronic questions under “Select an Application Type” users must select “Original” and then choose either, “Abbreviated New Animal Drug Application (ANADA)—under provisions of 512(b)(2) of the FD&C Act (21 U.S.C. 360b(b)(2))”; or “Abbreviated New Animal Drug Application—for certain combination pioneer products approved under provisions of 512(d)(4) of the FD&C Act (21 U.S.C. 360b(d)(4)).” If they select the first ANADA type, they will be charged 100 percent of the application fee. If they select the second ANADA type, then they will be charged at rate of 50 percent of the original application fee. To facilitate the application process in this regard, on Form FDA 3728 we have added a line in Section 3 that allows applicants to select the option, “3.2 Original Abbreviated New Animal Drug Application —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 Collection

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 Financial 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

Currently 90% of AGDUFA Cover Sheet Forms FDA 3728 are submitted electronically.

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, FDA would not be able to link payment of an abbreviated new animal drug application fee with an application that has been submitted.

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

In accordance with 5 CFR 1320.8(d), FDA published a 60-day notice for public comment in the Federal Register of February 18, 2014 (79 FR 9224). No comments were received.

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

This information collection does not contain questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1. -- Estimated Annual Reporting Burden

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

Respondents to this collection of information are new generic animal drug applicants. Based on Agency data for the past 3 years, FDA estimates there are approximately 40 submissions annually and a total of 3.2 burden hours.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Compliance Officer[1]	3.2	$46	$147.20

[1]May 2013 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, Compliance Officers 13-1041(www.bls.gov/oes/current/naics4_325400.htm) $35.24 hourly wage plus 30% adjusted for benefits.

FDA estimates that the total annual cost to respondents will be $147.20 (3.2 hours X $46 per hour).

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 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

There is no change in burden.

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.