FOOD AND DRUG ADMINISTRATION

Animal Generic Drug User Fee Act Cover Sheet

OMB Control No. 0910-0632

SUPPORTING STATEMENT

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 Animal Generic Drug User Fee Act (AGDUFA) cover sheet, which is designed to collect 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.

   We request extension of OMB approval of the information collection provisions of the Animal Generic Drug User Fee cover sheet (Form FDA 3728).

2. Purpose and Use of the Information Collection

   As noted, the AGDUFA cover sheet (Form FDA 3728) is designed to collect 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 form, when completed electronically, will result in the generation of a unique payment identification number used by FDA to track the payment. FDA's Center for Veterinary Medicine and FDA's Office of Financial Management will use the information collected to initiate the administrative screening of generic new animal drug applications to determine whether payment has been received.

   Description of Respondents: Respondents to this collection of information are new animal drug applicants. Respondents are from the private sector (for-profit businesses).

3. Use of Improved Information Technology and Burden Reduction

   Currently, 90% of AGDUFA cover sheets on Form FDA 3728 are submitted electronically. Form FDA 3728 is electronically fillable and fileable. The form does not

require a signature so it is not electronically signable. Instead, users are identified by their user name and password.

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

   There is no exemption from the Animal Generic Drug User Fee Act for small businesses. We assist small businesses to meet the requirements of the FD&C Act through our Regional Small Business Representatives and through the scientific and administrative staff within the Center. FDA estimates that approximately 2 of the affected firms are small businesses.

6. Consequences of Collecting the Information Less Frequently

   Data collection occurs occasionally. There are no specific regulatory time frames imposed on an applicant for submitting an application. If this information is not collected, FDA would not be able to link payment of an application fee with an application that has been submitted. The review of an application would not begin because concurrent submission of user fees with applications is required.

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

   There are no special circumstances associated with 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 September 2, 2016 (81 FR 60707). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

   We do not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

    We expect that abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs will contain trade secret and commercial confidential information. As a result, all files are maintained in a secured area. Confidentiality of the information submitted under these reporting requirements is protected under 21 CFR 514.11. Only information that is releasable under the agency's regulations in 21 CFR part 20 would be released to the public. This information is also safeguarded by section 301(j) of the FD&C Act and would be protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b)).

11. Justification for Sensitive Questions

    This information collection does not involve questions of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

FDA estimates the burden of this collection of information as follows:

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.

12 b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Cost
Compliance Officer[1]	3.2	$48	$153.60

[1]May 2013 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, Compliance Officers 13-1041 (http://www.bls.gov/oes/current/oes131041.htm) $36.82 hourly wage plus 30% adjusted for benefits.

FDA estimates that the total annual cost to respondents will be $153.60 (3.2 hours X $48 per hour).

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

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

14. Annualized Cost to the Federal Government

We estimate the cost to the Federal government to respond to the current level of AGDUFA cover sheets is approximately $201.57. This is based on an average hourly wage of a GS-13-3 level in the locality pay area of Washington-Baltimore-Arlington in 2017, $ 48.45/hour. Increasing this wage by 30% to account for overhead costs ($14.54), FDA estimates the average hourly cost to be $62.99/hour. The overall estimated cost is $201.57 (3.2 burden hours x $62.99/hour = $201.57).

15. Explanation for Program Changes or Adjustments

The burden has not changed from the burden shown in the current inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

We have no plans to tabulate and publish information from this information collection.

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

We are not seeking an exemption from displaying the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.