FOOD AND DRUG ADMINISTRATION

Animal Drug User Fee Cover Sheet

OMB Control No. 0910-0539

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-12), the Food and Drug Administration (FDA) has the authority to assess and collect application fees from each person who submits certain new animal drug applications or certain supplemental animal drug applications. The Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to assure that each animal drug user fee payment is appropriately linked to the animal drug application for which payment 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. FDA's Center for Veterinary Medicine and FDA's Office of Management will use the information collected to initiate the administrative screening of new animal drug applications and supplements to determine whether the payment has been received.

We request extension of OMB approval of the information collection provisions of the Animal Drug User Fee cover sheet (Form FDA 3546).

2. Purpose and Use of the Information Collection

As noted, the Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to assure that each animal drug user fee payment is appropriately linked to the animal drug application for which payment 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. FDA's Center for Veterinary Medicine and FDA's Office of Management will use the information collected to initiate the administrative screening of new animal drug applications and supplements to determine whether the payment has been received.

3. Use of Improved Information Technology and Burden Reduction

Form 3546 is an electronic form within an agency information technology system that determines the amount of user fee owed based on information the user submits. All submitters must prepare Form FDA 3546 online (100%). There is no paper version of the format that can be filled out. After preparation of the form, 90% of submitters choose to submit their ADUFA Cover Sheet on Form FDA 3546 electronically as part of an electronic application. The remaining 10% of submitters choose to print their ADUFA Cover Sheet on Form FDA 3546 and submit it with a paper application. Form FDA 3546 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

Section 740(d)(1)(E) of the FD&C Act provides that FDA shall grant a waiver from or a reduction of one or more of the fees where FDA finds that the sponsor involved is a small business submitting its first animal drug application to [FDA] for review. A "small business" is one that has fewer than 500 employees, including employees of affiliates. Section 740(d)(3)(A) of the FD&C Act. FDA developed a guidance entitled “Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.” This document provides guidance on, among other subjects, how to request waivers and reductions from FDA's animal drug user fees. In addition, 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. 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 October 21, 2016 (81 FR 72810). 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 new animal drug applications and supplements will contain trade secret and confidential commercial 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[1]

FD&C Act section; description	FDA Form No.	Number of Respondents	Number of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
740(a)(1); Animal Drug User Fee cover sheet	FDA 3546	21	1	21	1	21

The estimates in table 1 are based on our experience with new animal drug applications and supplemental animal drug applications and the average number of Animal Drug User Fee cover sheets submitted during fiscal years 2013-2015. We estimate 21 respondents will each submit a cover sheet (Form FDA 3546), for a total of 21 responses. We calculate a reporting burden of 1 hour per response, for a total of 21 hours.

12 b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Cost
Compliance Officer[1]	21	$47.87	$1005.27

[1]May 2015 National Industry-Specific Occupational Employment and Wage Estimates, US Department of Labor, Bureau of Labor Statistics, Compliance Officers 13-1041 (https://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 $1005.27 (21 hours x $47.87 per hour). The cost to respondents is based on the salary of a compliance officer, at a pay rate of $47.87 per hour, who is responsible for filling out, signing, and submitting the request. This salary estimate includes benefits but no overhead costs.

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 Animal Drug User Fee cover sheets is approximately $39,860. This is based on the salary of half an FTE at the GS-12/Step 1 level in the locality pay area of Washington-Baltimore-Arlington in 2017 ($79,720 /year) (0.5 FTE x $79,720 = $39,860).

15. Explanation for Program Changes or Adjustments

The collection includes an adjustment in the agency estimate. We have increased both the number of annual hours and responses by 4 to reflect an increase in submissions to the agency.

16. Plans for Tabulation and Publication and Project Time Schedule

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. We have no plans to tabulate and publish other 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.