Animal Drug User Fees (ADUFA) Cover Sheet FDA Form 3546
OMB Control No. 0910-0539
SUPPORTING STATEMENT, Part A

JUSTIFICATION

Terms of Clearance: None

1. Circumstances Making the Collection of Information Necessary

ADUFA was signed into law on November 18, 2003 (P. L 108-130), and the appropriation act enabling FDA to collect the newly authorized fees was signed into law on January 23, 2004. ADUFA requires FDA to collect new animal drug application fees from each person who submits certain new animal drug applications or supplements on or after September 1, 2003 (Section 740(a)(1)(A).

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

FORM FDA 3546

2. Purpose and Use of the Information Collection

The types of fees that require a cover sheet are certain new animal drug application fees and certain supplemental new animal drug application fees. The cover sheet (Form FDA 3546) is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each new animal drug user fee payment and each new animal drug application for which payment is made is appropriately linked to the payment that 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. It will be used by FDA's Center for Veterinary Medicine and FDA's Office of Management to initiate the administrative screening of new animal drug applications and supplements to determine if payment has been received.

3. Use of Improved Information Technology and Burden Reduction

Currently 90% of ADUFA Cover Sheet Forms FDA 3546 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. Small businesses account for approximately 2% of the animal drug sponsors.

6. Consequences of Collecting the Information Less Frequently

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.

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

There are no special circumstances for the collection of information requirements.

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 on February 3, 2014 (79 FR 6199) in the Federal Register. 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 sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

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

Table 1. -- Estimated Annual Reporting Burden1

Section of the Act as amended by ADUFA	Number of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
740(a)(1) FDA Form 3546 (Cover Sheet)	17	1 time for each application	17	1	17

[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 animal drug applicants or manufacturers. Based on FDA's data base system, there are an estimated 173 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the average number of submissions received by FDA in fiscal years 2011-2013. The estimated hours per response are based on past FDA experience with the various submissions. The hours per response are based on the average of these estimates.

12b. Annualized Cost Burden Estimate

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Cost
Compliance Officer[1]	17	$46	$782

[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 $782 (17 hours X $46 per hour). The cost to respondents is based on the salary of a compliance officer, at a pay rate of $46 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 and start-up, or operation, maintenance and purchase costs associated with this information collection.

14. Annualized Cost to the Federal 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 = $47,485.

15. Explanation for Program Changes or Adjustments

There is a decrease in burden from the last collection of information data. This is due to a smaller number of applications in the past three years. Our previous estimate of an average of 76 submissions annually appears to have been incorrect, while we believe our current estimate more accurately reflects the current burden and may be attributed to the streamlining of agency tracking resources and improved database management.

16. Plans for Tabulation 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. No other information will be published. This information collection is an ongoing project and therefore does not have a completion date.

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.