SUPPORTING STATEMENT
Animal Drug User Fees and Fee Waivers and Reductions
OMB# 0910-0540

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Enacted on November 18, 2003, ADUFA (Public Law 108-130) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and requires the FDA to assess and collect user fees for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from or a reduction of those fees in certain circumstances.

This information collection relates to Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions. The purpose of this document is to provide guidance on the types of fees the Food and Drug Administration (FDA or the Agency) is authorized to collect under the Animal Drug User Fee Act of 2003 (ADUFA) and how to request waivers and reductions from FDA's animal drug user fees. This guidance describes the types of fees and fee waivers and reductions; what information FDA recommends be submitted in support of a request for a fee waiver or reduction; how to submit such a request; and FDA's process for reviewing requests.

2. Purpose and Use of the Information

An animal drug application or supplemental animal drug application submitted by a person subject to application fees is considered incomplete and will not be accepted for filing by FDA until all fees owed by such person have been paid. Section 740(e) of the FD&C Act.

The purpose of collecting this information is to provide persons subject to fees an opportunity to obtain a waiver or reduction of certain animal drug user fees in advance of the submission of certain applications or in advance of the invoicing of the other annual fees.

3. Use of Information Technology and Burden Reduction

The Center for Veterinary Medicine (CVM, the Center) is accepting electronic 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.

ADUFA includes a waiver provision for small businesses. Businesses that have been granted a waiver of fees under this provision can note their exclusion from the fee requirement by utilizing the information contained in this guidance.

6. Consequences of Collecting the Information Less Frequently

If this information is not collected, the person subject to animal drug user fees would be required to have all fees, including 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 the collection of information requirements.

8. Consultations Outside FDA

In accordance with 5 CFR 1320.8(d), on June 14, 2007, in volume 72, No. 114, page 32851, a 60-day notice for public comment (Attachment 1) was published in the Federal Register. One comment was received, but it did not relate to the proposed information collection.

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 Hour Burden Including Annualized Hourly Costs

Table 1. -- Estimated Annual Reporting Burden[1]

FD&C Section Types of Waiver or Reduction Requests	Number of Respondents	Annual Frequency per Response	Total annual Responses	Hours per Response	Total Hours
740(d)(1)(A) Significant Barrier to Innovation	5	1 time for each application	5	2	10
740(d)(1)(B) Fees Exceed Cost	1	"	1	2	2
740 (d)(1)(C) Free Choice Feeds	5	"	5	2	10
740(d)(1)(D) Minor Use or Minor Species	10	"	10	2	20
740 (d)(1)(E) Small Business	2	"	2	2	4
Request for Reconsideration of a Decision	5	"	5	2	10
Request for Review - (User Fee Appeal Officer)	2	"	2	2	4
Total					60

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 drugs sponsors. Based on FDA's data base system, there are an estimated 250 sponsors of products subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver request is based on the number of submissions types received by FDA in fiscal year 2003. CVM estimates 30 waiver requests that include the following: 5 significant barriers to innovation, 1 fee exceed cost, 5 free choice feeds, 10 minor use or minor species, 2 small business waiver requests, 5 request for reconsideration of a decision, and 2 request for user fee appeal officer. The estimated hours per response are based on past FDA experience with the various waiver requests in CDER. The hours per response are based on the average of these estimates.

13. Estimated Annual Cost to Respondents

Activity	No. of Hours	Cost per Hour	Total Cost
Reporting	60	$35	$2100

FDA estimates that the total annual cost to respondents will be $2100 in 2004 (60 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.

14. Estimated Annual Cost to 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 $84,691 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. $84,691 times .50 = $42,346.

15. Changes in Burden

There is no change in burden from the 2004 collection of information data.

16. Publication of Results

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.

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.