Animal Drug User Fees and Fee Waivers and Reductions
OMB Control No. 0910-0540
Supporting Statement Part A

TERMS OF CLEARANCE: None

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

Enacted on November 18, 2003, and reauthorized by Congress in 2008 and 2013, 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.

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

2. Purpose and Use of the Information Collection

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 Improved Information Technology and Burden Reduction

At this time, requests for a fee waiver or reduction may not be 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.

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. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), on February 25, 2014 (79 FR 10532), a 60-day notice for public comment (Attachment 1) was published 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

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1 – Estimated Annual Reporting Burden[1]

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21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(d)(1)(A); significant barrier to innovation	45	1 time for each application	45	2	90
740(d)(1)(B); fees exceed cost	8	3.75	30	[2] 0.5	15
740(d)(1)(C); free choice feeds	5	1 time for each application	5	2	10
740(d)(1)(D); minor use or minor species	76	1 time for each application	76	2	152
740(d)(1)(E); small business	3	1 time for each application	3	2	6
Request for reconsideration of a decision	2	1 time for each application	2	2	4
Request for review—(user fee appeal officer)	0	1 time for each application	0	0	0
Total					277

Based on FDA's database system, from fiscal years 2010 to 2012 there were an estimated 173 sponsors 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 requests is based on the average number of submission types received by FDA in fiscal years 2010 to 2012.

12b. Annualized Cost Burden Estimate

Type of Respondent	No. of Hours	Cost per Hour	Total Cost
Animal Drug Sponsors	277	$35	$9695

FDA estimates that the total annual cost to respondents will be $9695 (277 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.

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

There are no other costs to respondents or recordkeepers.

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 an increase in burden for this collection of information data as more sponsors are taking advantage of the waiver benefit.

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. 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.