



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-N-0037]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Act Waivers and Reductions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0540. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASstaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Drug User Fees and Fee Waivers and Reductions

OMB Control Number 0910-0540--Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (Pub. L. 108-130) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding section 740 of the FD&C Act (21 U.S.C 379j-12), which requires that FDA assess and collect user fees with respect to new animal drug applications 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. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled “Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.” This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA’s animal drug user fees. Further, this guidance also 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. FDA uses the information submitted by respondents to determine whether to grant the requested fee waiver or reduction.

Respondents to this collection of information are new animal drug sponsors. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed, including application fees, product fees, establishment fees, or sponsor fees.

In the Federal Register of October 17, 2016 (81 FR 71506), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

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

Table 1.--Estimated Annual Reporting Burden¹

FD&C Act Section/Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
740(d)(1)(A); significant barrier to innovation	55	1 time for each application	55	2	110
740(d)(1)(B); fees exceed cost	8	3.75	30	.5 (30 minutes)	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	69	1 time for each application	69	2	138
740(d)(1)(E); small business	1	1 time for each application	1	2	2
Request for reconsideration of a decision	1	1 time for each application	1	2	2
Request for review (user fee appeal officer)	0	1 time for each application	0	0	0
Total					277

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on FDA's database system, from fiscal year (FY) 2014 to 2016 there were an estimated 177 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 FY 2014 to 2016. The burden has not changed since the last OMB approval.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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