4160-01-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 oira_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: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, PRAStaff@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 (ADUFA) (Pub. L. 108-130) amended the Federal Food, Drug, and Cosmetic Act and requires 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. 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.

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 February 25, 2014 (79 FR 10532) FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1--Estimated Annual Reporting Burden[1]

21 CFR Section; Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. 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	0.5 (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	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

[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 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.

Dated: May 12, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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