4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the paperwork burden of requesting a waiver or reduction of fees under Animal Drug User Fee Act (ADUFA).

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to http://www.regulations.gov. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the 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: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 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.

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	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	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 year (FY) 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 FY 2010-2012.

Dated: February 20, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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