DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0186]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the 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 (the PRA).

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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: Fumie Yokota, Desk Officer for FDA, FAX 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 4B–41, Rockville, MD 20857, 301–827–1472.

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), (Public Law 108–130) amended the Federal Food, Drug, and Cosmetic Act (the 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—application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of May 3, 2004 (69 FR 24169), FDA published a 60-day notice requesting comment on the collection of information. In response to that notice, no comments were received regarding the collection of information.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section of the Act Types of Waiver or Reduction Requests	No. 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.

Based on FDA's database 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 requests is based on the number of submissions types received by FDA in fiscal year 2003. The Center for Veterinary Medicine 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 requests for reconsideration of a

decision, and 2 requests for user fee appeal officers. The estimated hours per response are based on past FDA experience with the various waiver requests in the Center for Drug Evaluation and Research. The hours per response are based on the average of these estimates.

Dated: October 8, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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