**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**[Docket No. 2004N–0185]**

# Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Cover Sheet

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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:** 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 Fee Cover Sheet; FDA Form 3547 (OMB Control Number 0910–0539)—Extension**

Under section 740 of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Animal Drug User Fee Act (ADUFA) (21 U.S.C. 379j–12), FDA has the authority to assess and collect certain animal drug user fees. Because the submission of user fees concurrently with applications and supplements is required, review of an application cannot begin until the fee is submitted. Under the new statutory provisions (section 740(e) of the act, as amended by ADUFA), animal drug applications and supplemental animal drug applications for which the required fee has not been paid are considered incomplete and are not to be accepted for review by the agency. The types of fees that require a cover sheet are certain animal drug application fees and certain supplemental animal drug application fees. The cover sheet, FDA Form 3546, is designed to provide the minimum necessary information to determine whether a fee is required for the review of an application or supplement, to determine the amount of the fee required, and to assure that each animal drug user fee payment and each animal drug application for which payment is made, is appropriately linked to the payment that is made. The form, when completed electronically, will result in the generation of a unique payment identification number used in tracking the payment. FDA will use the information collected, to initiate administrative screening of new animal drug applications and supplements to determine if payment has been received. Inability to collect this information would delay the review process and would

also delay receipt of revenue that is to be used to fund the review of animal drug applications during the current fiscal year. Respondents to this collection of information are new animal drug applicants or manufacturers.

In the **Federal Register** of May 3, 2004 (69 FR 24168), 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 of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

| Section of the Act as Amended by ADUFA | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|---|---|---|---|---|
| 740(a)(1) FDA Form 3547 (Cover Sheet) | 69 | 1 time for each application | 69 | 1 | 69 |

[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 140 manufacturers of products or sponsors of new animal drugs potentially subject to ADUFA. However, not all manufacturers or sponsors will have any submissions in a given year and some may have multiple submissions. The total number of annual responses is based on the number of submissions received by FDA in the fiscal year 2003. FDA's Center for Veterinary Medicine, estimates 69 annual responses that include the following: 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per response are based

on past FDA experience with the various submissions and range from 30 minutes to 1 hour. The hours per response are based on the average of these estimates.

Dated: October 4, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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