

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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING<sup>1</sup>

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

<sup>1</sup> 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 fiscal year 2003. FDA's Center for Veterinary Medicine estimates 69 annual responses that include 28 new animal drug premarket approval applications and 41 supplements. The estimated hours per responses 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: April 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2004N-0186]

#### Agency Information Collection Activities; Proposed Collection; 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 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 reporting requirements for the animal drug user fees and fee waivers and reductions.

**DATES:** Submit written or electronic comments on the collection of information by July 2, 2004.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. 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:

Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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, 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 (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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

Section of the act Types of Waiver or Reduction Requests	No. of Respondents	Annual Fre- quency per Re- sponses	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

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

Based on FDA's data base 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 submission types received by FDA in fiscal year 2003. FDA's 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 officer. The estimated hours per response are based on past FDA experience with the various waiver requests in FDA's Center for Drug Evaluation and Research. The hours per response are based on the average of these estimates.

Dated: April 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 1999N-0193]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Supplements and Other Changes to an Approved Application

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled “Supplements and Other Changes to an Approved Application; Final Rule” has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of June 28, 1999 (64 FR 34608), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it

displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0538. The approval expires on March 31, 2007. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

At this time the agency has incorporated the information collection's reporting burden, previously identified by OMB control number 0910-0431, entitled “Changes to an Approved NDA or ANDA,” into this collection of information, identified by OMB control number 0910-0538.

Dated: April 23, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### National Vaccine Injury Compensation Program; List of Petitions Received

**AGENCY:** Health Resources and Services Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Health Resources and Services Administration (HRSA) is