information gathered since this collection was last reviewed in 2001, the agency has experienced that nine European manufacturers have not received any third-party requests for review annually. The agency estimates, based on dialog with EU officials and actual experience, nine firms will be designated to act as EU CABs.

2. Quality System Reports

Under this program, EU CABs will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./E.C. MRA and actual experience since the collection was last approved by OMB in 2001, the agency anticipates that European manufacturers will request third-party audits for approximately 36 medical device products annually. The agency estimates that 9 EU CABs will perform these evaluations.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 210 annual submissions of 510(k)s for third-party review.

As stated previously, firms designated as EU CABs will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such review will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each review. The agency anticipates that 45 premarket reports and 36 quality system reports will be generated and required to be maintained by EU CABs annually. The agency further estimates that each reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

Dated: October 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–23103 Filed 10–13–04; 8:45 am]

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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 November 15, 2004.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

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)(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.

[FR Doc. 04–23104 Filed 10–13–04; 8:45 am]

BILLING CODE 4160–01–S

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.

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 November 15, 2004.

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: