ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 502 FFD&C Act/Section 351 PHS Act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Glossary	1,742	1	1,742	4	6,968[2]
Educational Outreach	1,742	1	1,742	16	27,872
Total					34,840

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One time burden.

The glossary and educational outreach activities are inclusive of both domestic and foreign IVD manufacturers. The Center for Devices and Radiological Health's ''Information Retrieval System's Registration and Listing Information'' database listed the total number of IVD manufacturers as 1,742. From this total, 1,206 of the IVD manufacturers were listed as domestic and 536 were listed as foreign manufacturers. Consequently, FDA has based its burden estimate on the maximum possible number of manufacturers choosing to implement the use of symbols in labeling. The number of hours per response for the glossary and educational outreach activities were derived from consultation with a trade association and FDA personnel. The 4-hour estimate for a glossary is based on the average time necessary for a manufacturer to modify the glossary for the specific symbols used in labels or labeling for the IVDs manufactured. The 16-hour estimate for educational outreach, is inclusive of activities manufacturers used to educate the various professional users of IVDs regarding the meaning of the IVD symbols. Further, this estimate is based on FDA's expectation that IVD manufacturers will jointly sponsor many more educational outreach activities.

Dated: November 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22492 Filed 11–16–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0219]

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 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 December 19, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0540. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, 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–21 CFR Part 740 (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 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. 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 June 14, 2007 (72 FR 32851), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this collection of information are new animal drug sponsors.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	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	do.	1	2	2
740(d)(1)(C) Free choice feeds	5	do.	5	2	10
740(d)(1)(D) Minor use or minor species	10	do.	10	2	20
740(d)(1)(E) Small business	2	do.	2	2	4
Request for reconsideration of a decision	5	do.	5	2	10
Request for review—(user fee appeal officer)	2	do.	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 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: November 13, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22495 Filed 11–16–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No 2007N–0227]

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act

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 December 19, 2007.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974, or e-mailed to *baguilar@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0375. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, 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.

Medical Devices Third-Party Review Under the Food and Drug Administration Modernization Act; Section 523 of the Federal Food, Drug, and Cosmetic Act (OMB Control Number 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act (FDAMA) established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. Participation in this third-party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years. This information collection will allow FDA to continue to implement the accredited