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

person review program established by FDAMA and improve the efficiency of 510(k) review for low to moderate risk devices.

In the **Federal Register** of June 21, 2007 (72 FR 34257), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this information collection are businesses or other for-profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Section 523 of the act	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	1	1	1	24	24
510(k) reviews conducted by accredited third parties	14	24	336	40	13,440
Total					13,464

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Section 523 of the act	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews by third-party reviewers	14	24	336	10	3,600

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

I. Reporting

A. Requests for Accreditation

FDA now has approximately 8 years of experience with third-party reviews under section 523 of the act. Currently there are 11 active accredited third parties. FDA does not expect to receive more than 1 application for accreditation per year for a total of 14 accredited third parties who will be conducting third-party reviews.

B. 510(k) Reviews Conducted by Accredited Third Parties

FDA has received 784 510(k) submissions with a third-party review since 2004. FDA estimates that over the next 3 years, they will accredit 1 third-party reviewer per year for a total of 14 third parties. Each third-party reviewer expects to review a total of 24 510(k) submissions per year for an annual total of 336 applications.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. At the end of 3 years, the agency expects to have 14 accredited persons for review with each third party reviewing on average 24 510(k) applications per year. The agency anticipates approximately 336 510(k) annual submissions for third-party review.

Dated: November 14, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–22586 Filed 11–16–07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0305]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practice Regulations for Medicated Feeds

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 0910–0152. 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.

Current Good Manufacturing Practice Regulations for Medicated Feeds—21 CFR Part 225 (OMB Control Number 0910–0152)—Extension

Under section 501 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 351), FDA has the statutory authority to issue current good manufacturing practice (cGMP) regulations for drugs, including medicated feeds. Medicated feeds are administered to animals for the prevention, cure, mitigation, or treatment of disease, or growth promotion and feed efficiency. Statutory requirements for cGMPs have been codified under part 225 (21 CFR part 225). Medicated feeds that are not manufactured in accordance with these regulations are considered adulterated under section 501(a)(2)(B) of the act. Under part 225, a manufacturer is required to establish, maintain, and retain records for a medicated feed, including records to document procedures required during the manufacturing process to assure that proper quality control is maintained. Such records would, for example,