TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
226.42	115	260	29,000	0.75	22,425
226.58	115	260	29,000	1.75	52,325
226.80	115	260	29,000	0.75	22,425
226.102	115	260	24,000	1.75	52,325
226.110	115	260	29,000	0.25	7,475
226.115	115	10	1,150	0.5	575
Total					157,550

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

The estimate of the time required for record preparation and maintenance is based on agency communications with industry. Other information needed to calculate the total burden hours (i.e., manufacturing sites, number of type A medicated articles being manufactured, etc.) are derived from agency records and experience.

Dated: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24993 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0332]

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 10, 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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—(OMB Control Number 0910–0375)—Extension

Section 210 of the Food and Drug Administration Modernization Act of 1997 (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 reviews 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.

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

In the **Federal Register** of August 10, 2004 (69 FR 48508), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
Requests for accreditation	15	1	15	24	360
510(k) reviews conducted by accredited third parties	15	14	210	40	8,400
Totals					8,760

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews	15	14	210	10	2,100
Totals					2,100

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

The burdens are explained as follows:

I. Reporting

A. Requests for Accreditation

Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. In the past 3 years, the agency has averaged receipt of 15 applications for recognition of third-party review accredited persons. The agency has accredited 15 of the applicants to conduct third-party reviews.

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

In the 18 months under the third-party review pilot program, FDA received 22 submissions of 510(k)s that requested and were eligible for review by third parties. The agency has experienced that the number of 510(k)s submitted annually for third-party review since the last OMB approval in 2001 is approximately 210 annually, which is 14 annual reviews per each of the estimated 15 accredited reviewers.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)s for third-party review.

Dated: November 3, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–24994 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Advisory Committees; Filing of Annual Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing, as required by the Federal Advisory Committee Act, that the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2004.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20857, 301–827–6860.

FOR FURTHER INFORMATION CONTACT: Theresa L. Green, Committee Management Officer, Advisory Committee Oversight and Management Staff (HF–4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1220.

SUPPLEMENTARY INFORMATION: Under section 13 of the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR 14.60(c), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees through September 30, 2004:

Center for Biologics Evaluation and Research

Biological Response Modifiers Advisory Committee

Blood Products Advisory Committee

Vaccines and Related Biological Products Advisory Committee

Center for Drug Evaluation and Research

Anti-Infective Drugs Advisory Committee

Anesthetic and Life Support Drugs Advisory Committee

Dermatologic and Ophthalmic Drugs Advisory Committee

Nonprescription Drugs Advisory Committee

Center for Devices and Radiological Health

Medical Devices Advisory Committee (consisting of reports for the Dental Products Panel; Orthopaedic and Rehabilitation Devices Panel; Ophthalmic Devices Panel; Radiological Devices Panel)

Annual reports are available for public inspections between 9 a.m. and 4 p.m., Monday through Friday at the following locations:

1. The Library of Congress, Madison Bldg., Newspaper and Current Periodical Reading Room, 101 Independence Ave. SE., rm. 133, Washington, DC; and

2. The Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Dated: November 3, 2004.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 04–24996 Filed 11–9–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0468]

Draft Guidance for Industry on Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs for Use in Animals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance for industry (#123) entitled ''Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) for Use in Animals.'' This draft guidance is intended to provide specific advice regarding the development of target animal safety and effectiveness data to support approval of veterinary NSAIDs, specifically cyclooxygenase (COX) inhibitors.

DATES: Submit written or electronic comments on agency guidances by January 24, 2005 to ensure their adequate consideration in preparation of the final document. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.