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.