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.

Submit written comments on the draft guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http:///www.fda.gov/dockets/ecomments*. Comments should be identified with the full title of the draft guidance document and the docket number found in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:** Linda Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0135, e-mail: *lwilmot@cvm.fda.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

This draft guidance document provides information on approaches to the development of target animal safety and effectiveness data to support approval of veterinary NSAIDs—specifically, NSAIDs that reduce the production of prostaglandins by inhibiting the COX pathway. NSAIDs that inhibit lipooxygenase, or both lipooxygenase and COX, or act as cytokine antagonists. The Center for Veterinary Medicine (CVM) may recommend alternative product development strategies to complete its evaluation.

**II. Significance of Guidance**

This level 1 draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on the development of target animal safety and effectiveness data to support approval of non-steroidal anti-inflammatory drugs for use in animals. The document does not create or confer any rights for or on any person and will not operate to bind FDA or the public. Alternative methods may be used as long as they satisfy the requirements of the applicable statutes and regulations.

**III. Paperwork Reduction Act of 1995**

The collection of information requirements are approved by the Office of Management and Budget (OMB) under OMB control number 0910–0032.

**IV. Comments**

This draft guidance document is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this draft guidance document. Two paper copies of any mailed comments are to be submitted, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

**V. Electronic Access**

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [Docket No. 2004D–0468] ''Guidance for Industry on Development of Target Animal Safety and Effectiveness Data to Support Approval of Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) for use in Animals'' and follow the directions. Copies of this draft guidance may be obtained on the Internet from the CVM home page at *http://www.fda.gov/cvm*.

Dated: November 2, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04–24995 Filed 11–9–04; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Cancer Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Cancer Institute Special Emphasis Panel, EDRN: Biomarkers Reference Laboratories (EDRN:BRL).

*Date:* December 9, 2004.

*Time:* 12 p.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6130 Executive Blvd., Rockville, MD 20852 (Telephone Conference Call).

*Contact Person:* Timothy C. Meeker, MD, Scientific Review Administrator, Special Referral and Resources Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Boulevard, Room 8088, Rockville, MD 20852 (301) 594–1279.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower, 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: November 2, 2004.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

[FR Doc. 04–25016 Filed 11–9–04; 8:45 am]

**BILLING CODE 4140–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Center for Research Resources; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Center for Research Resources Special Emphasis Panel, Scientific and Technical Review Board.

*Date:* November 10, 2004.

*Time:* 10 a.m. to Adjournment.

*Agenda:* To review and evaluate grant applications.

*Place:* Office of Review, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Barbara J. Nelson, PhD, Office of Review, National Center for Research Resources, NIH, 6701 Democracy Blvd., Room 1080, 1 Democracy Plaza, Bethesda, MD 20892, (301) 435–0806.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.