

reviewers and government officials; staff evaluation and input; amount and duration of the grant requested and the proposed project's consistency and harmony with OCS goals and policy; geographic distribution of applications; previous program performance of applicants; compliance with grant terms under previous HHS grants, including the actual dedication to program of mobilized resources as set forth in project applications; audit reports; investigative reports; and applicant's progress in resolving any final audit disallowance on previous OCS or other Federal agency grants.

Approved But Unfunded

Applications: In cases where more applications are approved for funding than ACF can fund with the money available, the Grants Officer shall fund applications in their order of approval until funds run out. In this case, ACF has the option of carrying over the approved applications up to a year for funding consideration in a later competition of the same program. These applications need not be reviewed and scored again if the program's evaluation criteria have not changed. However, they must then be placed in rank order along with other applications in the later competition.

VI. Award Administration Information

1. Award Notices

Following approval of the application selected for funding, ACF will mail a written notice of project approval and authority to draw down project funds. The official award document is the Financial Assistance Award that specifies the amount of Federal funds approved for use in the project, the project and budget period for which support is provided and the terms and conditions of the award. The Financial Assistance Award is signed and issued via postal mail by an authorized Grants Officer.

ACF will notify unsuccessful applicants after the award is issued to the successful applicant.

2. Administrative and National Policy Requirements

Grantees are subject to the requirements in 45 CFR part 74 (non-governmental) or 45 CFR part 92 (governmental).

3. Reporting

All grantees are required to submit semi-annual program reports and semi-annual expenditure reports (SF-269) with final reports due 90 days after the project end date. A suggested format for the program report will be sent to all grantees after the awards are made.

VII. Agency Contacts

Program Office Contact: Dr. Margaret Washnitzer, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Myer Drive, Suite 300, Arlington, VA 22209, E-Mail: OCS@lcgnet.com, Phone: 1-800-281-9519.

Grants Management Office Contact: Barbara Ziegler Johnson, Team Leader, Office of Grants Management, Division of Discretionary Grants, Department of Health and Human Services (HHS), Administration for Children and Families, Office of Community Services Operations Center, 1815 Fort Myer Drive, Suite 300, Arlington, VA 22209, E-Mail: OCS@lcgnet.com, Phone: 1-800-281-9519.

VIII. Other Information

Additional information about this program and its purpose can be located on the following Web site: <http://www.acf.hhs.gov/programs/ocs>.

Dated: August 4, 2004.

Clarence H. Carter,

Director, Office of Community Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0332]

Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical devices; third-party review

under the Food and Drug Modernization Act of 1997 (FDAMA).

DATES: Submit written and electronic comments on the collection of information by October 12, 2004.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.fda.gov/dockets/ecomments>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501-3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices; Third-Party Review Under FDAMA (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.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

| | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|---|--------------------|-------------------------------|------------------------|--------------------|-------------|
| Requests for accreditation | 15 | 1 | 15 | 24 | 360 |
| 510(k) reviews conducted by accredited 3d 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 BURDEN¹

| | No. of Recordkeepers | Annual Frequency per Recordkeeper | 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: July 30, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cardiovascular and Renal Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Cardiovascular and Renal Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 10, 2004, from 8:30 a.m. to 5 p.m.

Location: Holiday Inn, Versailles Ballrooms, 8120 Wisconsin Ave., Bethesda, MD.

Contact Person: Dornette Spell-LeSane, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: spellesaned@cder.fda.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512533. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss new drug application (NDA) 21-686 proposed trade name EXANTA (ximelagatran) 24-milligram (mg) and