

1. The staff memo to the Board will be made available to the public in paper and the background material will be made available on a computer disc in Word format. If you require a paper copy of the document, please call Penelope Beattie on 202-452-3982.

2. This meeting will be recorded for the benefit of those unable to attend. Computer discs (CDs) will then be available for listening in the Board's Freedom of Information Office, and copies can be ordered for \$4 per disc by calling 202-452-3684 or by writing to: Freedom of Information Office, Board of Governors of the Federal Reserve System, Washington, D.C. 20551.

FOR FURTHER INFORMATION CONTACT: Michelle Smith, Director, or Dave Skidmore, Assistant to the Board, Office of Board Members at 202-452-2955.

SUPPLEMENTARY INFORMATION: You may call 202-452-3206 for a **recorded announcement** of this meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an **electronic announcement**. (The Web site also includes procedural and other information about the open meeting.)

Board of Governors of the Federal Reserve System, December 11, 2008.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. E8-29823 Filed 12-12-08; 11:15 am]

BILLING CODE 6210-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-0038]

Advisory Committees; Filing of Closed Meeting Reports

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that, as required by the Federal Advisory Committee Act, the agency has filed with the Library of Congress the annual reports of those FDA advisory committees that held closed meetings during fiscal year 2008.

ADDRESSES: Copies are available from the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 10(d) of the Federal Advisory Committee Act (5 U.S.C. app.1) and 21 CFR 14.60(d), FDA has filed with the Library of Congress the annual reports for the following FDA advisory committees that held closed meetings during the period October 1, 2007, through September 30, 2008:

Center for Biologics Evaluation and Research:

Blood Products Advisory Committee,
Cellular, Tissue and Gene Therapies Advisory Committee,
Vaccines and Related Biological Products Advisory Committee,

Center for Drugs Evaluation and Research:

Anesthetic and Life Support Drugs Advisory Committee,
Oncologic Drugs Advisory Committee,

Center for Devices and Radiological Health:

Medical Devices Advisory Committee (consisting of reports for Circulatory Drugs Devices Panel, Obstetrics and Gynecology Devices Panel and the Radiological Devices Panel),

National Center for Toxicological Research:

Science Board to the National Center for Toxicological Research.

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: December 9, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-29679 Filed 12-15-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0512]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices: Humanitarian Use Devices

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 January 15, 2009.

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 oir_submissions@omb.eop.gov. All comments should be identified with the OMB control number 0910-0332. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3793.

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: Humanitarian Use Devices—21 CFR Part 814 (OMB Control Number 0910-0332)—Extension

This collection of information implements the humanitarian use device (HUD) provision of section 520(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(m)) and subpart H, part 814 (21 CFR part 814). Under section 520(m) of the act, FDA is authorized to exempt a HUD from the effectiveness requirements of sections 514 and 515 of the act (21 U.S.C. 360d and 360e) provided that the device: (1) Is used to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States; (2) would not be

available to a person with such a disease or condition unless an exemption is granted, because there is no comparable device other than another HUD approved under this exemption that is available to treat or diagnose the disease or condition; and (3) will not expose patients to an unreasonable or significant risk of illness or injury with the probable benefit to health from using the device outweighing the risk of injury or illness from its use. This takes into account the probable risks and

benefits of currently available devices or alternative forms of treatment.

The information collected will assist FDA in making determinations on the following: (1) Whether to grant HUD designation of a medical device; (2) exempt a HUD from the effectiveness requirements under sections 514 and 515 of the act, provided that the device meets requirements set forth under section 520(m) of the act; and (3) whether to grant marketing approval(s) for the HUD. Failure to collect this information would prevent FDA from

making a determination on the factors listed previously in this document. Further, the collected information would also enable FDA to determine whether the holder of a HUD is in compliance with the HUD provisions under section 520(m) of the act.

In the **Federal Register** of October 1, 2008 (73 FR 57108), 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 BURDEN¹

| 21 CFR Section | No. of Respondents | Annual Frequency per Response | Total Annual Responses | Hours Per Response | Total Hours |
|----------------|--------------------|-------------------------------|------------------------|--------------------|-------------|
| 814.102 | 14 | 1 | 14 | 40 | 560 |
| 814.104 | 6 | 1 | 6 | 320 | 1,920 |
| 814.106 | 6 | 2 | 12 | 50 | 600 |
| 814.108 | 32 | 1 | 32 | 80 | 2,560 |
| 814.116(e)(3) | 1 | 1 | 1 | 1 | 1 |
| 814.124(a) | 5 | 1 | 5 | 1 | 5 |
| 814.124(b) | 4 | 1 | 4 | 2 | 8 |
| 814.126(b)(1) | 45 | 1 | 45 | 120 | 5,400 |
| Total | | | | | 11,054 |

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

| 21 CFR Section | No. of Recordkeepers | Annual Frequency per Recordkeeping | Total Annual Records | Hours Per Record | Total Hours |
|----------------|----------------------|------------------------------------|----------------------|------------------|-------------|
| 814.126(b)(2) | 45 | 1 | 45 | 2 | 90 |
| Total | | | | | 90 |

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

The number of respondents in tables 1 and 2 of this document are an average from data for the previous 3 years, i.e., fiscal year 2005–2007. The number of annual reports submitted under § 814.126(b)(1) in table 1 reflects an increase to 45 respondents with approved HUD applications. Likewise, under § 814.126(b)(2) in table 2, the number of recordkeepers increased to 45.

Dated: December 9, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–29672 Filed 12–15–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0633]

Agency Information Collection Activities; Proposed Collection; Comment Request; Postmarketing Adverse Drug Experience Reporting

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 collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on postmarketing adverse drug experience reporting and recordkeeping requirements.

DATES: Submit written or electronic comments on the collection of information by February 17, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets