

ESTIMATED ANNUAL RESPONDENT BURDEN—Continued

Survey	Number of respondents *	Estimated time per respondent in minutes	Estimated total burden hours
2nd Quarter	500	10	83.33
3rd Quarter	500	10	83.33
Annual Total	1500	250

* The estimate for number of respondents for the initial implementation is 100 per quarter. The estimate included in the table assumes wider implementation by the Agency.

Estimated Annual Costs to the Federal Government

The annual cost to the government is \$100,000 for licensing, support and maintenance.

Request for Comments

In accordance with the above-cited Paperwork Reduction Act legislation, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Carolyn M. Clancy,
Director.

[FR Doc. 07-4577 Filed 9-14-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Notice of Meetings

In accordance with section 10(d) of the Federal Advisory Committee Act as amended (5 U.S.C., Appendix 2), the Agency for Healthcare Research and Quality (AHRQ) announces meetings of

scientific peer review groups. The subcommittees listed below are part of the Agency's Health Services Research Initial Review Group Committee.

The subcommittee meetings will be closed to the public in accordance with the Federal Advisory Committee Act, section 10(d) of 5 U.S.C., Appendix 2 and 5 U.S.C. 552b (c)(6). Grant applications are to be reviewed and discussed at these meetings. These discussions are likely to involve information concerning individuals associated with the applications, including assessments of their personal qualifications to conduct their proposed projects. This information is exempt from mandatory disclosure under the above-cited statutes.

1. *Name of Subcommittee:* Health Systems Research.

Date: October 18, 2007 (Open from 8 a.m. to 8:15 a.m. on October 18 and closed for remainder of the meeting).

Place: Agency for Healthcare Research and Quality (AHRQ), John Eisenberg Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

2. *Name of Subcommittee:* Health Care Research Training.

Date: October 18-19, 2007 (Open from 9 a.m. to 9:15 a.m. on October 18 and closed for remainder of the meeting).

Place: Agency for Healthcare Research and Quality (AHRQ), John Eisenberg Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

3. *Name of Subcommittee:* Health Care Quality and Effectiveness Research.

Date: October 24, 2007 (Open from 8 a.m. to 8:15 a.m. on October 24 and closed for remainder of the meeting).

Place: Agency for Healthcare Research and Quality (AHRQ), John Eisenberg Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

4. *Name of Subcommittee:* Health Care Technology and Decision Sciences.

Date: October 25-26, 2007 (Open from 8 a.m. to 8:15 a.m. on October 25 and closed for remainder of the meeting).

Place: Agency for Healthcare Research and Quality (AHRQ), John Eisenberg Conference Center, 540 Gaither Road, Rockville, Maryland 20850.

Contact Person: Anyone wishing to obtain a roster of members, agenda or minutes of the nonconfidential portions of the meetings should contact Mrs. Bonnie Campbell, Committee Management Officer, Office of Extramural Research, Education and Priority Populations, AHRQ, 540 Gaither Road, Suite 2000, Rockville, Maryland 20850, Telephone (301) 427-1554.

Agenda items for these meetings are subject to change as priorities dictate.

Carolyn M. Clancy,
Director.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-07-07AD]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call the CDC Reports Clearance Officer at (404) 639-5960 or send an e-mail to omb@cdc.gov. Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC or by fax to (202) 395-6974. Written comments should be received within 30 days of this notice.

Proposed Project

Formative Research to Inform an HIV Testing Social Marketing Campaign for African American Heterosexual Men—New collection—National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Coordinating Center for Infectious Diseases (CCID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

This project involves formative research to inform the development of the HIV Testing Social Marketing Campaign for African American Heterosexual Men, a CDC-sponsored social marketing campaign aimed at increasing HIV testing rates among young, single, African American men. The study entails conducting focus groups and interviews with a sample of single African American heterosexual men, ages 18 to 44, with less than 4 years of college education to: (1) Explore participants' knowledge, attitudes and

beliefs about HIV and HIV testing to inform the development of campaign messages; (2) identify the most motivating approach, supporting data, and key messages for materials development; (3) test creative concepts, potential campaign themes, logos and names; and (4) test creative materials developed based on the findings from the previous phases of the research. Findings from this study will be used by CDC and its partners to inform current and future program activities.

We expect 153 participants to be screened for eligibility annually. Of the 153 participants who are screened, we

anticipate that 72 will participate. The 72 participants will be divided; 36 participating in focus groups and 36 participating in interviews. Additionally, all focus group and interview participants will complete a short "Paper and Pencil" questionnaire. This is a burden hour reduction from the 60 Day **Federal Register** Notice which estimated the annual number of respondents at 306, with 153 participating; 81 in focus groups and 72 in interviews. There are no costs to the respondents other than their time. The total estimated annual burden hours are 146.

ESTIMATED ANNUALIZED BURDEN HOURS AND BURDEN TABLE

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Screener	153	1	10/60
Focus Group	36	1	2
Interview	36	1	1
Paper and Pencil Survey	72	1	10/60

Dated: September 7, 2007.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N-0231]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Premarket Approval of Medical 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 October 17, 2007.

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 baguilar@omb.eop.gov. All comments should be identified with the OMB control number 0910-0073. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

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:

Premarket Approval of Medical Devices—21 CFR Part 814 and Food and Drug Administration Modernization Act Sections 201, 202, 205, 208, and 209 (OMB Control Number 0910-0231)—Extension

Section 515 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e) sets forth the requirements for premarket approval of certain class III medical devices. Class III devices are either preamendments devices that have been classified into class III, or postamendments devices which are not substantially equivalent to a preamendments device, or transitional devices. Class III devices are devices such as implants, life sustaining or life supporting devices, devices that are of substantial importance in preventing

impairment of human health, and devices that otherwise present a potentially unreasonable risk of illness or injury. Most premarket approval application (PMAs) are for postamendments class III devices.

Under section 515 of the act, an application must contain certain specific information, including full reports of all information concerning investigations showing whether the device is reasonably safe and effective. The application should also include a statement of components, ingredients, and properties of the principles of operation for such a device. In addition, the application should also include a full description of the methods used in, and the facilities and controls used for, the manufacture and processing of the device and labeling specimens. The implementing regulations, contained in part 814 (21 CFR part 814), further specify the contents of a PMA for a class III medical device and the criteria FDA sets forth in approving, denying, or withdrawing approval of a PMA as well as supplements to PMAs. The purpose of these regulations is to establish an efficient and thorough procedure for FDA's review of PMAs and supplements to PMAs for certain class III (premarket approval), medical devices. The regulations under part 814 facilitate the approval of PMAs and supplements to PMAs for devices that have been shown to be reasonably safe and effective and otherwise meet the statutory criteria for approval. The regulations also ensure