

involving individual Federal Reserve System employees.

2. Any items carried forward from a previously announced meeting.

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 beginning at approximately 5 p.m. two business days before the meeting for a recorded announcement of bank and bank holding company applications scheduled for the meeting; or you may contact the Board's Web site at <http://www.federalreserve.gov> for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, July 14, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-06-06BL]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and instruments, call 404-639-5960 and

send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to omb@cdc.gov.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection 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 on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

Evaluation of the HIV Testing Social Marketing Campaign (HTSMC)—New—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 the evaluation of the HIV Testing Social Marketing Campaign (HTSMC), a CDC-sponsored social marketing campaign aimed at increasing HIV testing rates among young, single, African American women. The CDC has designed an efficacy study to evaluate the HTSMC and its messages under controlled conditions. The study entails selecting a sample of single African American females, ages 18 to 34, with less than 4 years of college education and collecting baseline data on their knowledge, attitudes, beliefs, intentions, and behaviors related to HIV testing. The study represents an "efficacy" methodology in that participants will be divided into treatment and control

conditions. Participants in the treatment condition, will be exposed to campaign materials including radio advertisements, a billboard, and an informational booklet that will be distributed over the Internet. Thus the study participants' exposure will occur under controlled conditions, without the distractions and variability of potential exposure in the real world. As part of the advertisement stimuli package, the billboard advertisement will appear as part of the online log-in for each stimuli session in order to simulate the appearance of a sign. Therefore, we do not estimate any additional burden for exposure to the billboard advertisement.

Key outcomes related to the HTSMC will be measured in two follow-up surveys. The first follow-up survey will occur 2 weeks after the baseline survey. The second follow-up survey will occur 6 weeks after the baseline survey. Comparisons of changes in these outcomes would then be made between participants in the treatment and control conditions. Findings from this study will be used by CDC and its partners to inform current and future program activities.

We expect a total of 1,630 participants to complete the baseline survey. The 1,630 participants who complete the baseline survey will be randomly assigned to the treatment or control condition. 815 participants (the treatment condition) will be exposed to the radio ad and booklet. Of the 1,630 participants who completed the baseline survey, we expect 1,140 to complete the first follow-up survey. Of the 1,140 who complete the first follow-up survey, we expect 800 to complete the second follow-up survey, which will have fewer questions than the first follow-up survey because it will only pertain to questions about behavior change and selected behavioral intentions.

There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Responses per respondent	Average burden per response (in hours)	Total burden hours
Baseline survey	1,630	1	15/60	408
Radio ad stimuli viewing	815	1	18/60	245
Booklet reading	815	1	15/60	204
Follow-up survey 1	1,140	1	15/60	285
Follow-up survey 2	800	1	5/60	67
Total				1,209

Dated: July 10, 2006.

Joan F. Karr,

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. 2004D-0333]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Draft Guidance: Emergency Use Authorization of Medical Products

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 August 17, 2006.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. 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.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

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.

Draft Guidance: Emergency Use Authorization of Medical Products

The Federal Food, Drug, and Cosmetic Act (the act) permits the Commissioner of FDA (the Commissioner) to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the act (21 U.S.C. 360bbb-3). The data to support issuance of an emergency use

authorization (EUA) must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb-3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the act, the Commissioner may establish conditions on the approval of an EUA. Section 564(e) requires the Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that he finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the act also gives the Commissioner authority to establish other conditions on an authorization that the Commissioner finds to be necessary or appropriate to protect the public health.

For purposes of estimating the burden of reporting, FDA has established six

categories of respondents which include: (1) Those who file a Request for Consideration for an EUA after a determination of actual or potential emergency and, in lieu of submitting the data, provide reference to a pending or approved application; (2) those who file a Request for Consideration for an EUA and the data after a determination of actual or potential emergency, without reference to a pending or approved application; (3) those who submit data to FDA on a candidate EUA product, which is subject to a pending or approved application, prior to a determination of actual or potential emergency; (4) those who submit data to FDA prior to a determination of actual or potential emergency about a candidate EUA product for which there is no pending or approved application; (5) manufacturers of an unapproved EUA product who must report to FDA regarding such activity; and (6) State and local public health officials who carry out an activity related to an unapproved EUA product (e.g., administering the product to civilians) and who must report to FDA regarding such activity.

For purposes of estimating the burden of recordkeeping, FDA has calculated the anticipated burden on manufacturers of unapproved products authorized for emergency use. The agency anticipates that the Federal Government will perform some of the additional recordkeeping necessary for unapproved products (e.g., related to the administration of unapproved EUA products to military personnel). FDA also anticipates that some State and local public health officials may be required to perform additional recordkeeping (e.g., related to the administration of unapproved EUA products to civilians) and calculated a recordkeeping burden for those activities.

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, because those products already are subject to approved collections of information (adverse experience reporting for biological products is approved under OMB control number 0910-0308 through May 31, 2005; adverse drug experience reporting is approved under OMB control number 0910-0230 through September 30, 2005; and investigational new drug applications (IND) regulations are approved under OMB control number 0910-0014 through January 31, 2006), and any additional burden imposed by this proposed collection would be minimal. Thus, FDA estimates the burden of this collection of information as follows: