

Type of respondent	Number of respondents	Responses per respondent	Hours per response	Total annual burden hours
Total .....	42,750	.....	.....	6,662.50

Written comments and recommendations concerning the proposed information collection should be sent by February 26, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-5806.

Dated: January 19, 2010.

**Elaine Parry,**

*Director, Office of Program Services.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Disease Control and Prevention**

[60Day-10-10BA]

**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 or send comments to Maryam Daneshvar, CDC Reports Clearance Officer, 1600 Clifton Road, MS-D74, Atlanta, GA 30333 or send an e-mail to [omb@cdc.gov](mailto: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**

Development and Testing of an HIV Prevention Intervention Targeting Black Bisexually-Active Men—new—National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

African Americans continue to be disproportionately affected by HIV/AIDS. Results from the National HIV Behavioral Surveillance Project published in the June 2006 Morbidity and Mortality Weekly Reports showed that during 2001-2004, although African-Americans accounted for approximately 13 percent of the population, they accounted for the majority (51 percent) of HIV/AIDS diagnoses in 33 states. Black men who have sex with men (MSM) have been identified as the population segment with the highest rates of HIV infection in the U.S. and as a population in need of new HIV prevention interventions. Previous research indicates that 20% to 40% of Black MSM also have female sex

partners. Interventions developed for gay men may not be relevant or appropriate for men who have sex with men and women (MSMW), many of whom do not self-identify as gay and who may need different prevention strategies for their male and female partners. No interventions in the scientific literature with demonstrated efficacy in reducing HIV-related sexual risk behaviors have been developed and evaluated specifically for African-American MSMW. The proposed study is essential for developing effective HIV/AIDS prevention interventions for at-risk African-American MSMW and for informing policies and programs that will more effectively protect them and their partners from infection.

The purpose of the proposed study is to develop and pilot-test three novel behavioral interventions to reduce sexual risk for HIV infection and transmission among African-American MSMW who do not inject drugs. Eligible respondents will be recruited using chain referral sampling techniques. Three study sites (Public Health Management Corporation (PHMC), Nova Southeastern University, and California State University (CSU) at Dominguez Hills) will use a randomized controlled trial to evaluate the effectiveness of the intervention. Respondents will be reimbursed up to a total of \$300 for their time and for completing all data collection forms. If these interventions are found to be effective, organizations that implement risk-reduction interventions will be able to use the curricula to intervene with this population more successfully. Ultimately, the beneficiary of this data collection will be African-American MSMW at risk for HIV. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN TABLE

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
Prospective Participant .....	Screening Instrument .....	1,250	1	5/60	104
Enrolled Participant .....	Locator Form .....	750	1	10/60	125
Enrolled Participant-PHMC .....	Baseline Assessment .....	250	1	1	250
Enrolled Participant-Nova .....	Baseline Assessment .....	240	1	1	240
Enrolled Participant-CSU .....	Baseline Assessment .....	260	1	1	260
Enrolled Participant-PHMC .....	Acceptability Survey .....	250	6	10/60	250
Enrolled Participant-Nova .....	Acceptability Survey .....	240	1	10/60	40

ESTIMATE OF ANNUALIZED BURDEN TABLE—Continued

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total annual burden (in hours)
Enrolled Participant-CSU .....	Acceptability Survey .....	260	1	10/60	43
Enrolled Participant-PHMC .....	Immediate Follow-Up Assessment ..	225	1	30/60	113
Enrolled Participant-Nova .....	Immediate Follow-Up Assessment ..	216	1	30/60	108
Enrolled Participant-CSU .....	Immediate Follow-Up Assessment ..	234	1	30/60	117
Enrolled Participant-PHMC .....	3 month Follow-Up Assessment .....	200	1	1	200
Enrolled Participant-Nova .....	3 month Follow-Up Assessment .....	192	1	1	192
Enrolled Participant-CSU .....	3 month Follow-Up Assessment .....	208	1	1	208
Total .....	.....	.....	.....	.....	2,250

Dated: January 20, 2010.  
**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. FDA-2010-D-0026]

**Draft Guidance for Industry on Assessment of Abuse Potential of Drugs; Availability**

**AGENCY:** Food and Drug Administration, HHS.  
**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Assessment of Abuse Potential of Drugs.” This draft guidance is intended to assist sponsors who are developing drug and other medical products with the potential for abuse that may need to be scheduled under the Controlled Substances Act. Drugs with abuse potential generally include drugs that affect the central nervous system, drugs that are chemically or pharmacologically similar to other drugs with known abuse potential, and drugs that produce psychoactive effects such as sedation, euphoria, or mood change.  
**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by March 29, 2010.  
**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

**FOR FURTHER INFORMATION CONTACT:**

Corinne P. Moody, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 5144, Silver Spring, MD 20993-0002, 301-796-5402.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance for industry entitled “Assessment of Abuse Potential of Drugs.” Under the Federal Food, Drug, and Cosmetic Act, an abuse potential assessment is part of the general evaluation of the safety and efficacy of a drug to be used under medical supervision. If a drug has abuse potential, the Secretary of Health and Human Services (HHS) is required under the Controlled Substances Act of 1970 (CSA) to make a recommendation for scheduling to the Drug Enforcement Administration (DEA). The regulatory responsibilities for this process are described in Title 21 United States Code (U.S.C.) 811, with delegation of authority to FDA from HHS. The Controlled Substance Staff (CSS) of FDA performs the scientific evaluation of the abuse potential of a drug for HHS, in consultation with the National Institute on Drug Abuse (NIDA), as described in a Memorandum of Understanding (MOU) of March 8, 1985 (50 FR 9518).

When a sponsor submits a marketing application for a drug with abuse potential to FDA for review, the sponsor is required to propose a CSA schedule and provide a basis for this proposal (21 CFR 314.50(d)(5)(vii)). The sponsor’s proposal is considered by the agency during its evaluation of the drug’s abuse potential. At the time a marketing application is submitted to FDA for review, the sponsor signs a statement agreeing not to market the product until the DEA makes a final scheduling decision.

FDA prepares a scientific analysis with a recommendation for scheduling, based on the submission of the sponsor that includes a scientific and medical evaluation of all relevant and available data, an assessment of the public health risk, and a proposal for scheduling. This recommendation is forwarded to DEA for consideration in the decision on final scheduling of the drug. Scheduling results in specific regulatory requirements relating to the drug’s labeling, prescribing, advertising, manufacturing, promotion, marketing, and use in the practice of medicine. Not following these requirements can result in criminal penalties.

This draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency’s current thinking on assessing abuse potential of drugs. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

**II. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any