

Written comments and recommendations concerning the proposed information collection should be sent by July 29, 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: June 22, 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-10-10FB]

**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 Maryam I. Daneshvar, Ph.D., 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**

Developing a Sexual consent Norms Instrument—New—National Center for Injury Prevention and Control (NCIPC), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

Sexual violence prevention strategies are increasingly focusing on promoting positive behavioral norms such as safety, equality and respect in relationships, however psychometrically validated measures do not exist for programs to use in evaluating their strategies. This project provides an opportunity to significantly contribute to the literature base and fill a gap in evaluation tools by developing a measure specific to consent norms for use in three populations: college students, late adolescents (ages 15-18) and early adolescents (ages 11-14). Sound measures of sexual consent norms will improve program evaluation efforts and potentially contribute to understanding of effective prevention strategies as well as the etiology of sexual violence perpetration.

The development of these measures will occur in four phases. Phase one will consist of multiple two-hour focus groups of 8-10 participants: 1 with prevention educators, 8 with college students, 8 with late adolescents (ages 15-18) and 8 with early adolescents (ages 11-14). Samples of college students and adolescents will include Asian, Black and African American, Hispanic or Latino, and White students. Half of the college student focus groups will be conducted with students who grew up in the United States; the other half will be conducted with students who came to the United States within the last five years. Focus group participants will be asked to comment on the proposed instruments relevant to their group. Prevention educators will

comment on all three instruments. Comments will be used to refine the measures.

In phase two, 200 Asian, Black and African American, Hispanic or Latino, and White college students and 100 Asian, Black and African American, Hispanic or Latino, and White adolescents will complete the revised instrument appropriate to age group, plus a set of existing instruments that assess related variables, using online data collection methods.

Phase three will consist of multiple two-hour focus groups of 8-10 participants: 2 with prevention educators, 1 with college students, 1 with late adolescents (ages 15-18) and 1 with early adolescents (ages 11-14). Samples of college students and adolescents will include Asian, Black and African American, Hispanic or Latino, and White students as well as students who grew up in the United States and students who came to the United States in the last five years. All focus group participants will be asked to comment on data collected with the revised instruments in their age group. Prevention educators will be asked to comment on data from all age groups. Comments will be used to refine the instrument again, before administering it to larger samples.

In phase four, the refined instruments plus a set of existing instruments that assess related variables will be administered to 500 Asian, Black and African American, Hispanic or Latino, and White college students and 400 Asian, Black and African American, Hispanic or Latino, and White adolescents (200 early adolescents and 200 late adolescents). Data collection will occur via an online survey. These data will be used to examine the psychometric properties of the new instruments.

Findings will be used to demonstrate the adequacy of new instruments for use in racially and ethnically diverse populations of college student and adolescents by sexual assault prevention programs funded through the Rape Prevention and Education Program. There is no cost to respondents other than their time.

**ESTIMATED ANNUALIZED BURDEN HOURS**

Respondents/form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (in hrs)
Phase I: Focus Group of Prevention Educators .....	10	1	3	30
Phase I: Focus Group of College Students .....	10	1	2.5	25
Phase I: Focus Group of Late Adolescents .....	10	1	3	30
Phase I: Focus Group of Early Adolescents .....	10	1	3	30

ESTIMATED ANNUALIZED BURDEN HOURS—Continued

Respondents/form name	Number of respondents	Number of responses per respondent	Average burden per response (hours)	Total burden (in hrs)
Phase II: College Student Survey .....	200	1	2	400
Phase II: Late Adolescent Survey .....	50	1	2	100
Phase II: Early Adolescent Survey .....	50	1	1	50
Phase III: Follow-up Focus Group of Prevention Educators .....	20	1	3	60
Phase III: Follow-up Focus Group of College Students .....	10	1	2.5	25
Phase III: Follow-up Focus Group of Late Adolescents .....	10	1	3	30
Phase III: Follow-up Focus Group of Early Adolescents .....	10	1	3	30
Phase IV: Confirmatory Survey of College Students .....	500	1	2	1000
Phase IV: Confirmatory Survey of Late Adolescents .....	200	1	2	400
Phase IV: Confirmatory Survey of Early Adolescents .....	200	1	1	200
<b>Total</b> .....				<b>2410</b>

Dated: June 23, 2010.  
**Carol Walker,**  
*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-0094]

**Draft Guidance: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals; Availability**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance (#209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” This draft guidance is intended to inform the public of FDA’s current thinking on the use of medically important antimicrobial drugs in food-producing animals.

**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 either electronic or written comments on the draft guidance by August 30, 2010.

**ADDRESSES:** Submit written requests for single copies of the guidance to the Communications Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-

addressed adhesive label to assist that office in processing your requests. Additional copies of this guidance are available from the Office of Communication, Outreach and Development (OCOD) (HFM-40), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, or by calling 1-800-835-4709 or 301-827-1800, or e-mail: [ocod@fda.hhs.gov](mailto:ocod@fda.hhs.gov). See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. 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.

**FOR FURTHER INFORMATION CONTACT:** William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-276-9084, e-mail: [william.flynn@fda.hhs.gov](mailto:william.flynn@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA is announcing the availability of a draft guidance (#209) entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals.” Antimicrobial drugs have been widely used in human and veterinary medicine for more than 50 years, with tremendous benefits to both human and animal health. The development of resistance to this important class of drugs, and the resulting loss of their effectiveness as antimicrobial therapies, poses a serious public health threat. Misuse and overuse of antimicrobial drugs creates selective evolutionary pressure that enables antimicrobial resistant bacteria to increase in numbers more rapidly

than antimicrobial susceptible bacteria and thus increases the opportunity for individuals to become infected by resistant bacteria. Because antimicrobial drug use contributes to the emergence of drug resistant organisms, these important drugs must be used judiciously in both animal and human medicine to slow the development of resistance. Using these drugs judiciously means that unnecessary or inappropriate use should be avoided. Although efforts to assure judicious use should be directed at all uses of antimicrobial drugs, the focus of this document is on the use of medically important antimicrobial drugs in food-producing animals.

In regard to the use of antimicrobial drugs in animals, concerns have been raised by the public and components of the scientific and public health communities that a significant contributing factor to antimicrobial resistance is the use of medically important antimicrobial drugs in food-producing animals for production or growth-enhancing purposes. This document summarizes some of the key scientific reports on the use of antimicrobial drugs in animal agriculture and outlines FDA’s current thinking on strategies for assuring that medically important antimicrobial drugs are used judiciously in food-producing animals in order to help minimize antimicrobial resistance development.

Based on a consideration of the available scientific information, FDA is making a number of recommendations regarding the appropriate or judicious use of medically important antimicrobial drugs in food-producing animals. These recommendations include phasing in such measures as follows: (1) Limiting medically important antimicrobial drugs to uses in food-producing animals that are considered necessary for assuring