

the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the National Institutes of Health (NIH). The Task Force also includes the Agency for Healthcare Research and Quality (AHRQ), the Centers for Medicare and Medicaid Services (CMS), the Health Resources and Services Administration (HRSA), the HHS Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR), the Department of Agriculture (USDA), the Department of Defense (DoD), the Department of Veterans Affairs (VA), and the Environmental Protection Agency (EPA).

In 2001, the Task Force developed an initial Action Plan, outlining specific issues, goals, and actions important for addressing the problem of AR. This document, entitled *A Public Health Action Plan to Combat Antimicrobial Resistance, Part I: Domestic Issues*, reflected a broad-based consensus of participating Federal agencies, which was reached with individual input from State and local health agencies, universities, professional societies, pharmaceutical companies, healthcare delivery organizations, agricultural producers, consumer groups, and other members of the public. Continued collaboration with these partners has been vital to achieving successful implementation of the Action Plan.

This draft document, *A Public Health Action Plan to Combat Antimicrobial Resistance*, is a revision of the 2001 interagency action plan. The revised Action Plan provides an updated blueprint for specific, coordinated Federal action to address emerging threats in AR. The document covers a broad spectrum of AR issues, addressing resistance in a wide range of pathogens (bacteria, viruses, fungi, and parasites) and settings (human medicine, veterinary medicine, agriculture, animal production, and others).

The Action Plan includes action items organized into four focus areas: Surveillance, Prevention and Control, Research, and Product Development. The Action Plan contains specific action items, projects, and implementation steps. Wherever possible, action items are populated with specific projects or implementation steps to provide greater specificity for planned Federal activities. The action items, projects,

and implementation steps do not represent an exhaustive list of activities.

Dated: March 11, 2011.

Tanja Popovic,

*Deputy Associate Director for Science,
Centers for Disease Control and Prevention.*

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity: Comment Request

Title: Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

OMB No.: New collection.

Description: The Family Youth Services Bureau (HHS/ACF/ACYF/FYSB) and the Office of Planning Research and Evaluation (HHS/ACF/OPRE) in the Administration for Children and Families (ACF) are proposing three data collection activities to be undertaken for the Personal Responsibility Education Program (PREP) Multi-Component Evaluation.

The impact study included in the PREP Multi-Component Evaluation is a random assignment evaluation which will expand available evidence on whether the replication of evidence-based effective programs, or the substantial incorporation of elements of these programs, funded as part of the Personal Responsibility Education Program, are effective at delaying sexual activity, increasing condom or contraceptive use for sexually active youth, or reducing pregnancy among youth. The evaluation will document and test a range of pregnancy prevention approaches in up to five program sites. The findings from the evaluation will be of interest to the general public, to policy-makers, and to organizations interested in teen pregnancy prevention.

This **Federal Register** Notice is to notify the public regarding Data Collection for the Baseline, Field Collection, and In-Depth Implementation Components of the Impact and In-Depth Implementation Evaluation of the Personal

Responsibility Education Program (PREP) Multi-Component Evaluation.

Field Collection: The field collection activity involves the collection of information from observations of program activities and interviews with a range of experts and persons involved with programs about various aspects of existing prevention programs and topics the experts view as important to address through evaluation. These data will be used to help enhance decisions about the types of programs to be evaluated in the studies.

In-Depth Implementation: The implementation data collection activity as part of the in-depth implementation portion of the PREP Multi-Component Evaluation involves the collection of information from program records and site visits at two to three points in the program implementation period. Understanding the programs, documenting their implementation and context, and assessing fidelity of implementation will allow for description of each implemented program and the treatment-control contrast evaluated in each site. It will also help in interpreting impact findings, differences in impacts across programs, and differences in impacts across locations or population subgroups.

Baseline: The baseline data collection activity will present respondents with carefully selected questions about demographics and risk and protective factors related to teen pregnancy. Also proposed is a collection of school records, performance, and program participation for the youth. Information from this data collection will be used to perform meaningful analysis to determine significant program effects.

Respondents:

Field Clearance: Researchers; Policy Experts; State Level Coordinators; Program Directors; Program Staff; Program Participants; School Administrators.

In-Depth Implementation: General Staff; Community Members; Frontline Staff; Participating Youth; and Control Group Schools.

Baseline: Study participants (*i.e.*, adolescents, and schools and organizations responsible for administrative data); Schools and Organizations.

ANNUAL BURDEN ESTIMATES

	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Field clearance instrument:				
Discussion Guide for use with Researchers, Policy Experts, and State Level Coordinators	10	1	1	10
Discussion Guide for Use with Program Directors	20	2	2	80
Discussion Guide for Use with Program Staff	40	1	2	80
Focus Group Discussion Guide for use with Program Participants	100	1	1.5	150
Discussion Guide for Use with School Administrators	70	1	1	70
Short Survey with Program Directors	70	1	0.25	17.5
Short Survey with Program Staff	140	1	0.25	35
Short Survey with School Administrators	70	1	0.25	17.5
Estimated Annual Burden Sub-total for Field Clearance				460
In-Depth Implementation Instrument:				
Master Topic Guide Interviews for General Staff and Community Members	40	1	1.5	60
Focus Group Discussion Guide with Frontline Staff	30	1	1.5	45
Focus Group Discussion Guide with Participating Youths	150	1	1.5	225
Focus Group Discussion Guide with Control Group Schools About Counterfactuals	40	1	1	40
Estimated Annual Burden Sub-total for In-Depth Implementation				370
Baseline Instrument:				
Baseline Instrument for study participants	2500	1	.5	1250
Administrative Data Collection instrument for Schools and Organizations	100	1	4	400
Estimated Annual Burden Sub-total for Baseline				1650
TOTAL Estimated Annual Burden				2640

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. E-mail address: OPREinfocollection@acf.hhs.gov. All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: March 9, 2011.

Steven M. Hanmer,
Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0541]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; Guidance for Industry on Special Protocol Assessment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled "Guidance for Industry on Special Protocol Assessment" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT:

Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3792, Elizabeth.Berbakos@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of October 26, 2010 (75 FR 65636), the Agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910-0470. The