

CDC plans to obtain public preferences for the framing and dissemination of Chlamydia information that will guide CDC in developing and testing health communication messages about Chlamydia with girls/women in the following age groups: 15–17 year olds who attend school (n = 54) and,

15–17 year olds who do not attend school (n = 18), totaling 72. 18–25 years who are employed (n = 27) and, 18–25 year olds who attend school full time (n = 27), totaling 54. We will also include parents of girls 15–17 years old (n = 72). We will interview 126 respondents from the screened groups. We will recruit

participants throughout the United States and conduct interviews by telephone or in person at local pre-determined focus group facility. There are no costs to the respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Responses per respondent	Average burden per response (in hours)	Total burden hours
Participant Screenings	Ages 15–17 attending school	72	1	5/60	6
	Ages 15–17 not attending school				
	Ages 18–25 employed	54	1	5/60	5
Parent Screening Interviews	Ages 18–25 attending school full time				
	Parent(s) of 15–17 yr olds	72	1	5/60	6
Participant Interviews	Selected 15–25 yr olds	126	1	2	252
Total Burden Hours					269

Dated: October 22, 2007.

Maryam I. Daneshvar,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-08–0406]

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

State and Local Area Integrated Telephone Survey (SLAITS), (OMB No. 0920–0406)—Extension—National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 306 of the Public Health Service (PHS) Act (42 U.S.C. 242k), as amended, authorizes that the Secretary of Health and Human Services (DHHS), acting through NCHS, shall collect statistics on the extent and nature of illness and disability of the population of the United States. The State and Local Area Integrated Telephone Survey (SLAITS) mechanism has been conducted since 1997. NCHS requests 3 years of OMB clearance to continue using this integrated and coordinated survey system. It is specifically designed to collect health and well-being data at the national, state, and local levels (in accordance with the 1995 initiative to increase the integration of surveys within DHHS).

Using the large sampling frame from the ongoing National Immunization Survey (NIS) and Computer Assisted Telephone Interviewing (CATI), SLAITS has quickly collected and produced household and person-level data to monitor many health-related areas. The questionnaire content is drawn from

existing surveys within DHHS and other Federal agencies. Depending on the needs of the project sponsor, a new instrument may need to be developed. Examples of topical areas are child and family health and well-being; early childhood health; children with special health care needs (CSHCN); influenza vaccination of children; asthma prevalence and treatment; access to care; program participation; the health and well-being of adopted children; post-adoption support use; knowledge of Medicaid and the State Children's Health Insurance Program (SCHIP); and changes in health care coverage at the national and state levels.

Since its inception the SLAITS mechanism has been used by federal, state, and local government researchers and policymakers; researchers at universities and non-profit groups; and advocates to evaluate content and programmatic health issues. For example, the CSHCN and Children's Health modules have been used by Federal and state Maternal and Child Health Bureau Directors to evaluate programs and service needs. The module on Medicaid and SCHIP was prominently featured in a Congressional report on children's insurance.

There is no cost to respondents other than their time to participate. The total estimated annualized burden hours are 55,190.

ESTIMATED ANNUALIZED BURDEN

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Developmental work—Household screener	14,535	1	3/60
Developmental work—Household screener & survey	6,151	1	28/60
Main implementation—Household screener	515,027	1	3/60
Main implementation—Household screener & survey	59,635	1	26/60

Dated: October 17, 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. 2007D-0393]

Draft Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility" dated October 2007. The draft guidance document provides assistance to blood establishments in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. In the **Federal Register** of March 9, 2005 (70 FR 11679), FDA withdrew the guidance document entitled "Draft Guideline for the Validation of Blood Establishment Computer Systems," issued on September 28, 1993, and is issuing this guidance to reflect our current considerations on this topic.

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 January 28, 2008.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and

Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling CBER at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

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 either <http://www.fda.gov/dockets/ecomments> or <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT:

Brenda R. Friend, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft document entitled "Guidance for Industry: Guidance for Industry: Blood Establishment Computer System Validation in the User's Facility" dated October 2007. This draft guidance provides blood establishments with assistance in developing a blood establishment computer system validation program, consistent with recognized principles of software validation, quality assurance, and current good software engineering practices. This draft guidance addresses blood establishment computer system validation rather than blood establishment computer software (BECS) validation. In the **Federal Register** of March 9, 2005, FDA withdrew the guidance document entitled "Draft Guideline for the Validation of Blood Establishment Computer Systems," issued on September 28, 1993, and is issuing this guidance to reflect our current considerations on this topic.

The draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent FDA's current thinking on this topic. 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 requirement of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 606.100(b) and 606.160 have been approved under OMB control number 0910-0116; those in 21 CFR 211.68 have been approved under OMB control number 0910-0139.

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.