

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN FOR TYPE A MEDICATED ARTICLES¹—Continued

	No. of Respondents	Annual Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
Total Burden Hours					210

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Significance of Guidance

This draft level 1 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the agency's current thinking on the topic.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 alternate method may be used as long as it satisfies the requirements of applicable statutes and regulations.

IV. Comments

This draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this draft guidance document. Two paper copies of any comments are to be submitted, except that individuals may submit one paper copy. Comments should be identified with the docket number found in brackets in the heading of this document. A copy of the document 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.

V. Electronic Access

Copies of the draft guidance document entitled "Waivers of *In Vivo* Demonstration of Bioequivalence of Certain Animal Drugs in Soluble Powder Oral Dosage Form Products and Type A Medicated Articles" may be obtained from the CVM home page at <http://www.fda.gov/cvm> and from the Division of Dockets Management Web site <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: July 27, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are 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.

Proposed Project: Voluntary Customer Satisfaction Surveys to Implement Executive order 12862 in the Substance Abuse and Mental Health Services Administration (SAMHSA)—OMB No. 0930-0197; Extension)—Executive Order 12862 directs agencies that "provide significant services directly to the public" to "survey customers to determine the kind and quality of services they want and their level of satisfaction with existing services." SAMHSA provides significant services directly to the public, including treatment providers and State substance abuse and mental health agencies, through a range of mechanisms, including publications, training, meetings, technical assistance and web sites. Many of these services are focused on information dissemination activities. The purpose of this submission is to extend the existing generic approval for such surveys.

The primary use for information gathered is to identify strengths and weaknesses in current service provisions by SAMHSA and to make improvements that are practical and feasible. Several of the customer satisfaction surveys expected to be implemented under this approval will provide data for measurement of program effectiveness under the Government Performance and Results Act (GPRA). Information from these customer surveys will be used to plan and redirect resources and efforts to improve or maintain a high quality of service to health care providers and members of the public. Focus groups may be used to develop the survey questionnaire in some instances.

The estimated annual hour burden is as follows:

Type of data collection	Number of respondents	Responses/respondent	Hours/response	Total hours
Focus groups	150	1	2.50	375
Self-administered, mail, telephone and e-mail surveys	16,000	1	.33	5,280
Total	16,150			5,655

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer,

Room 16-105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

Written comments should be received by October 4, 2004.

Dated: July 27, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

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DEPARTMENT OF HOMELAND SECURITY

Border and Transportation Security; Notice to Aliens Included in the United States Visitor and Immigrant Status Indicator Technology System (US-VISIT)

AGENCY: Border and Transportation Security Directorate, DHS.

ACTION: Notice.

SUMMARY: The Department of Homeland Security (DHS) has established the United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT), an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. On January 5, 2004, DHS implemented the first phase of US-VISIT by publishing an interim final rule in the **Federal Register** at 69 FR 468 authorizing DHS to require certain aliens to provide fingerprints, photographs, or other biometric identifiers upon arrival in or departure from the United States at air and sea ports of entry. The January 5 interim final rule also authorized the Secretary of Homeland Security (Secretary) to establish pilot programs at up to fifteen air or sea ports of entry, to be identified by notice in the **Federal Register**, through which DHS may require certain aliens who depart from a designated air or sea port of entry to provide specified biometric identifiers and other evidence at the time of departure. On January 5, 2004, DHS published a notice in the **Federal Register** at 69 FR 482 identifying one air and one sea port of entry designated for US-VISIT inspection at the time of alien departure to initiate the US-VISIT exit pilot program.

This notice informs the public of the implementation of US-VISIT exit pilot programs at an additional thirteen air or sea ports as authorized under 8 CFR 215.8(a). This notice further provides a complete listing of the fifteen air and sea ports where US-VISIT exit pilot programs are in operation. This notice also introduces new data collection processes and describes the process under which the exit pilot programs will be evaluated by DHS.

DATES: Effective Dates: This notice is effective August 3, 2004.

FOR FURTHER INFORMATION CONTACT: Michael Hardin, Program Analyst, US-VISIT, Border and Transportation Security, Department of Homeland Security, 425 I Street, NW., Washington, DC 20536, telephone (202) 298-5200.

SUPPLEMENTARY INFORMATION:

Background

What Is US-VISIT?

DHS established the United States Visitor and Immigrant Status Indicator Technology Program (US-VISIT) in accordance with several Congressional mandates requiring that DHS create an integrated, automated entry-exit system that records the arrival and departure of aliens; verifies aliens' identities; and authenticates aliens' travel documents through comparison of biometric identifiers. US-VISIT is part of a continuum of security measures that begins overseas, when a person applies for a visa to travel to the United States, and continues on through entry and exit at U.S. air and seaports and, eventually, at land border crossings. The US-VISIT program enhances the security of U.S. citizens and visitors by verifying the identity of visitors with visas. At the same time, the program facilitates legitimate travel and trade by leveraging technology and the evolving use of biometrics to expedite processing at U.S. borders.

The goals of the program are to:

- Enhance the security of U.S. citizens and visitors.
- Facilitate legitimate travel and trade.
- Ensure the integrity of the immigration system.
- Safeguard the personal privacy of visitors.

On January 5, 2004, DHS published an interim final rule in the **Federal Register** at 69 FR 468 implementing the first phase of US-VISIT at air and sea ports of entry in the United States. The January 5 interim final rule authorized the Secretary to:

- Require nonimmigrant aliens seeking admission pursuant to a nonimmigrant visa at an air or sea port of entry designated by notice in the **Federal Register** to provide fingerprints, photograph(s), or other specified biometric identifiers at time of application for admission or at time of departure; and
- Establish pilot programs at up to fifteen air or sea ports of entry, designated through notice in the **Federal Register**, through which the Secretary or his delegate may require an alien admitted pursuant to a

nonimmigrant visa who departs the United States from a designated air or sea port of entry to provide fingerprints, photograph(s), or other specified biometric identifiers, documentation of his or her immigration status in the United States, and such other evidence as may be requested to determine the alien's identity and whether he or she has properly maintained his or her status while in the United States.

On January 5, 2004, DHS also published a notice in the **Federal Register** identifying which aliens are subject to or exempt from the US-VISIT requirements, the information that would be required from those aliens, and the specific air and sea ports and locations which are designated for the collection of that information. The January 5 Notice also identified one airport and one seaport for collection of biometric information from aliens departing from the United States under the US-VISIT exit pilot program.

What Does This Notice Do?

This notice informs the public of the implementation of US-VISIT departure pilot programs to thirteen additional air or sea ports, expanding the US-VISIT exit program to the full complement of fifteen air or sea ports authorized under 8 CFR 215.8. All aliens subject to 8 CFR 235.1(d)(1)(iii) will be required to provide fingerprints, photographs, or other specified biographic data when departing the United States from one of these additional ports.

As discussed in the January 5 interim final rule, DHS, through the exit pilot programs, will test different methods to collect the required information from aliens as they depart the United States through the designated ports of entry. DHS currently is exploring several different methods and processes for collection of information, including the existing self-serve kiosks already in place and hand-held scanners that can be taken from person to person by a DHS officer to collect biometric information. The exit pilot programs will enable the Department to conduct a cost-benefit analysis of the different processes for collection of biometric information and determine which process allows for the most accurate and efficient collection of information from aliens departing from the United States.

How Will the Pilot Program Process Be Evaluated?

The objective of the exit pilot program is to allow DHS to evaluate processes for obtaining biometric identifiers and other information from aliens departing the United States and determine which process provides the best method of