

stakeholders. The MAQC project will work with participating scientists to develop baseline practices for the analysis of hybridization data. Original datasets, analyses, and conclusions from this project will be made available to the public throughout the project. For more information about the MAQC project, please visit <http://www.fda.gov/nctr/science/centers/toxicoinformatics/maqc/>.

Dated: April 13, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2001N-0464 (formerly Docket No. 01N-0464)]

#### Vaccine Adverse Event Reporting; Revised Form VAERS-2; Withdrawal of Proposed Revised Form

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

**ACTION:** Notice; withdrawal.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the withdrawal of a proposed revised form that was issued in the **Federal Register** on November 20, 2001.

**DATES:** April 21, 2006.

**FOR FURTHER INFORMATION CONTACT:** Joseph L. Okrasinski, Jr., 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:** In a notice published in the **Federal Register** of November 20, 2001 (66 FR 58153), FDA announced the availability of a proposed revised form entitled "Vaccine Adverse Event Reporting System" (Form VAERS-2) dated July 2001. This proposed revised form is being withdrawn because FDA is no longer pursuing changes to the form.

Dated: April 12, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HOMELAND SECURITY

### United States Visitor and Immigrant Status Indicator Technology (US-VISIT) Program; Notice of Availability of a Final Programmatic Environmental Assessment (PEA) and a Finding of No Significant Impact (FONSI) on the US-VISIT Plan for Potential Changes to Immigration and Border Management Processes

**AGENCY:** US-VISIT, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** A Final Programmatic Environmental Assessment (PEA) and Finding of No Significant Impact (FONSI) for the United States Visitor and Immigrant Status Indicator Technology (US-VISIT) program are available to the public for electronic download. The Final PEA examines the potential environmental impacts of four strategic approaches to enhance immigration and border management processes and addresses the substantive comments received on the Draft PEA during the public comment period. These four approaches are aimed at improving information available to determine the identity and immigration status of individuals traveling to and from the United States. The Final PEA resulted in a FONSI that selected the proposed action, or Hybrid Alternative, as the approach to enhance the immigration and border management enterprise. The Final PEA and FONSI are made available to the public in accordance with the National Environmental Policy Act of 1969 (NEPA) and the Council on Environmental Quality (CEQ) regulations for implementing NEPA.

**DATES:** The Final PEA and FONSI will be available to the public on April 17, 2006.

**ADDRESSES:** Copies of the Final PEA and FONSI may be obtained by download through the Internet at <http://www.dhs.gov/us-visit>.

**FOR FURTHER INFORMATION CONTACT:** Lisa Mahoney, US-VISIT Environmental Program Manager, at (202) 298-5245, Monday-Friday, 8 a.m.—5 p.m. EDT.

**SUPPLEMENTARY INFORMATION:** US-VISIT published a Notice of Availability of a Draft Programmatic Environmental Assessment (PEA) on the US-VISIT Plan for Potential Changes to Immigration and Border Management Processes in the **Federal Register** (71 FR 8602, February 17, 2006). The Notice briefly discussed four strategic approaches analyzed in the Draft PEA, informed the public on how to obtain a copy of the

Draft PEA, requested comments from the public on the Draft PEA during the public commenting period, and informed the public on the location and time of public meetings in seven locations in the United States during the public comment period. The comment period ended on March 18, 2006. Thirty-two (32) comments were received and considered by US-VISIT.

The proposed action, or Hybrid Alternative, has been selected as the approach by which enhancements will be made to immigration and border management processes. This approach was selected after careful review of the environmental assessment and consideration of input received from the public and other federal and state agencies during the public comment period. The Hybrid Alternative was chosen because it provides the most opportunity for the entities responsible for immigration and border management to incorporate and balance the most useful components of the virtual and physical border alternatives to achieve security, facilitation, individual privacy, and immigration system integrity goals. A review of the relative impacts showed that no alternative would result in a significant impact and that the Hybrid Alternative ranked second in terms of environmental preference. As warranted, tiered environmental analyses for specific initiatives at the land border ports of entry resulting from selection of the Hybrid Alternative will be conducted and these tiered analyses will be made available to the public. A collection or "toolbox" of strategies and information for monitoring, mitigation, and environmental stewardship will also be developed to be used in implementing the Hybrid Alternative.

**Juan Reyes,**

*Director, Office of Safety and Environmental Programs, Department of Homeland Security.*

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## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[DHS-2005-0053]

#### Privacy Act of 1974; Systems of Records

**AGENCY:** Department of Homeland Security; United States Customs and Border Protection.

**ACTION:** Notice of revision to and expansion of Privacy Act system of records.

**SUMMARY:** This notice announces a revision to and expansion of a previously-established Privacy Act system of records, the Global Enrollment System, to facilitate the creation of a consolidated database to collect biometric and biographic data for individuals who voluntarily exchange personally identifiable information in return for expedited transit at U.S. border entry points. The Global Enrollment System will enhance transportation security by affording United States Customs and Border Protection, the system owner, the opportunity to perform advanced screening on low-risk trusted travelers and to expedite the security screening process of these trusted travelers as their low-risk status is confirmed.

**DATES:** The revised System of Records will be effective May 22, 2006, unless comments are received that result in a contrary determination. The public is invited to comment on the proposed System of Records.

**ADDRESSES:** You may submit comments, identified by docket number DHS-2005-0053 by one of the following methods:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Fax: (202) 572-8727.
- Mail: Border Security Regulations Branch, Office of Regulations and Rulings, Bureau of Customs and Border Protection, Mint Annex, Washington, DC 20229; Maureen Cooney, Acting Chief Privacy Officer, Department of Homeland Security, 601 S. 12th Street, Arlington, VA 22202-4220.

**FOR FURTHER INFORMATION CONTACT:** If you have any questions about this notice, please contact Laurence Castelli, Chief, Privacy Act Policy and Procedures Branch, U.S. Customs and Border Protection, Washington, DC 20229, Phone: (202) 572-8720, Fax (202) 572-8727; or Maureen Cooney, Acting Chief Privacy Officer, U.S. Department of Homeland Security, Arlington, VA 22202-4220, Phone: (571) 227-3813, Fax: (571) 227-4171.

**SUPPLEMENTARY INFORMATION:** United States Customs and Border Protection, a component agency of the Department of Homeland Security, currently operates multiple programs at Ports of Entry that offer individuals an expedited transit experience at United States security points in exchange for providing personally identifiable information to facilitate identification of the individual as a "trusted traveler." The personally identifiable information now collected for these programs is currently maintained in the Global Enrollment

System (GES), a Privacy Act system of records, notice of which was last published in the **Federal Register** on March 13, 1997, as Justice/INS-017 (62 FR 11919).

CBP inherited these Port of Entry expedited border-crossing programs upon the creation of DHS on March 1, 2003. These local programs were created by both the former Immigration and Naturalization Service and the former U.S. Customs Service to facilitate the regular and recurring border transit of individuals who voluntarily provide information to CBP in exchange for expedited processing at the border. The personally identifiable data collected for these programs is maintained in a legacy GES system, notice of which was originally published in the **Federal Register** at 62 FR 11919 on March 13, 1997 as Justice/INS-017.

CBP is now consolidating these various programs, which have operated locally, into a national system as a means for both expanding the expedited border crossing benefit to approved participants and achieving greater uniformity in the criteria for admission to these programs. The information to be collected will continue to be provided primarily by applicants, and will consist of biographic data sufficient for program purposes and biometric data—currently envisioned to be fingerprints and photographs—that will be used for identity verification. In order to complete the enrollment process, the information from applicants will be used to query law enforcement and other databases in order for CBP to decide if an individual can be accepted as a low-risk, "trusted traveler." There will be an opportunity for the individual to verify the accuracy of the information at enrollment. In addition, a redress program will be available so that if errors are made in decisions regarding applicants, a process is available to resolve these discrepancies.

An enterprise-wide Global Enrollment System (GES) will centralize the application and enrollment functions for these programs in a way that is efficient, integrated and scalable. The proposed revisions to GES are expected to be part of the process by which CBP and the entire Department of Homeland Security, acting in concert with the Department of State and our international partners, adopts 21st century technology to improve the security of our borders while facilitating travel by United States citizens and foreign visitors.

The Privacy Act (5 U.S.C. 552a) embodies fair information principles in a statutory framework governing the means by which the United States

Government collects, maintains, uses and disseminates personally identifiable information. The Act applies to information that is maintained in a "system of records." A "system of records" is a group of any records under the control of an agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

The Privacy Act requires each agency to publish in the **Federal Register** a description of the type and character of each system of records that the agency maintains, and the routine uses for which such information may be disseminated and the purpose for which the system is maintained. The revised and consolidated Global Enrollment System is described below.

In accordance with 5 U.S.C. 552a(r), a report of this revised system of records has been provided to the Office of Management and Budget (OMB) and to the Congress.

#### **DHS/CBP-002**

##### **SYSTEM NAME:**

Global Enrollment System (GES).

##### **SYSTEM LOCATION:**

This computer database is located at U.S. Customs and Border Protection (CBP) National Data Center in Washington, DC. Computer terminals are located at border ports of entry and airport and seaport inspection facilities under the jurisdiction of the Department of Homeland Security (DHS).

##### **CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Individuals who apply to use any form of automated or other expedited inspection for verifying eligibility to cross the borders into the United States.

##### **CATEGORIES OF RECORDS IN THE SYSTEM:**

The system contains application data such as full name, including nickname or other names used, place and date of birth, gender, current and former addresses, telephone numbers, country of citizenship, alien registration number (if applicable), employment history, biometric data, driver's license number and issuing state or province, the make, model, color, year, license number and license issuing state or province of the applicant's vehicle, the flag and home port (where the vessel is foreign flagged), name, registration number and registration issuing state or province of the applicant's vessel, the name and address of the vehicle's or vessel's registered owners if different from the applicant, and the amount of fee paid. The application may also include such

information as the frequency of border crossings or travel, and the most frequent reason for crossing the border or travel, information supplied by the applicant as to whether he or she has been arrested or convicted of any violations of law, and information obtained from checks of other law enforcement databases that would confirm or refute this information.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**  
8 U.S.C. 1101, 1103, 1201, 1304, and 1356.

**PURPOSE(S):**

Information in this system is used to adjudicate applications to enter the United States by any available form of automated or other expedited inspection, including that offered to travelers arriving in the United States via dedicated commuter lanes, to pedestrians and vehicles arriving at ports of entry, to pedestrians and vehicles arriving at other lands borders, and to air and sea travelers.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, all or a portion of the records or information contained in this system may be disclosed outside DHS as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

A. To Federal, State, local, foreign, international or tribal government agencies or organizations during the course of processing applications to elicit information necessary to make decisions on these applications.

B. To appropriate Federal, State, local, foreign, international or tribal government agencies or organizations that are lawfully engaged in collecting intelligence or law enforcement information (whether civil, criminal or administrative) and/or charged with investigating, prosecuting, enforcing or implementing civil and/or criminal laws, related rules, regulations or orders, to enable these entities to carry out their law enforcement and intelligence responsibilities.

C. To a Congressional office response to an inquiry from that Congressional office made at the request of the individual to whom the record pertains.

D. To the National Archives and Records Administration or other federal government agencies pursuant to records management inspections being conducted under the authority of 44 U.S.C. 2904 and 2906.

E. To the Department of Justice or other federal agency conducting

litigation or proceedings before any court, adjudicative or administrative body, when: (a) DHS, or (b) any employee of DHS in his/her official capacity, or (c) any employee of DHS in his/her individual capacity where DOJ or DHS has agreed to represent the employee, or (d) the United States or any agency thereof, is a party to the litigation or has an interest in such litigation.

F. To contractors, grantees, experts, consultants, volunteers, and others performing or working on a contract, service, grant, cooperative agreement, or other assignment for the Federal government, when necessary to accomplish an agency function related to this system of records.

G. To an agency, organization, or individual for the purposes of performing authorized audit or oversight operations.

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Application information is maintained in paper form and in an automated database in electronic format.

**RETRIEVABILITY:**

These records are retrieved by name, address, vehicle license number or other personal identifier.

**SAFEGUARDS:**

The system is protected through a multi-layer security approach. The protective strategies are physical, technical, administrative and environmental in nature and provide access control to sensitive data, physical access control to DHS facilities, confidentiality of communications, authentication of sending parties, and personnel screening to ensure that all personnel with access to data are screened through background investigations commensurate with the level of access required to perform their duties.

**RETENTION AND DISPOSAL:**

The legacy GES system provides that records will be destroyed three years after the denial of an application as a "trusted traveler" or after an issued permit expires. In light of the changes to the program that are envisioned, CBP will work with its Records personnel to develop an appropriate retention schedule that accounts for both operational and privacy concerns.

**SYSTEM MANAGER AND ADDRESS:**

Director, Passenger Systems Program Office, Office of Information and

Technology, 1300 Pennsylvania Ave., NW., Washington, DC 20229.

**NOTIFICATION PROCEDURES:**

To determine whether this system contains records relating to you, write to the CBP Customer Satisfaction Unit, Office of Field Operations, U.S. Customs and Border Protection, 1300 Pennsylvania Avenue, NW. (Room 5.5C), Washington, DC 20229.

**RECORDS ACCESS PROCEDURES:**

Requests for access must be in writing and should be addressed to CBP Customer Satisfaction Unit in the Office of Field Operations, or the DHS Director for Departmental Disclosure and FOIA. Requests should conform to the requirements of 6 CFR part 5, subpart B, which provides the rules for requesting access to Privacy Act records maintained by DHS. The envelope and letter should be clearly marked "Privacy Act Access Request." The request should include a general description of the records sought and must include the requester's full name, current address, and date and place of birth. The request must be signed and either notarized or submitted under penalty of perjury.

**CONTESTING RECORDS PROCEDURES:**

Same as Records Access Procedures above. State clearly and concisely the information being contested, the reasons for contesting it, and the proposed amendment to the information sought.

**RECORD SOURCE CATEGORIES:**

The primary source of information is the application. Other law enforcement records systems may be used as part of adjudicating the applications.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

Records and information in this system obtained from checks of other law enforcement databases are exempt from 5 U.S.C. 552a(c)(3), (c)(4), (d)(1), (d)(2), (d)(3), (d)(4), (e)(1), (e)(2), (e)(3), (e)(4)(G), (H), and (I), (5) and (8), (f), and (g) of the Privacy Act pursuant to 5 U.S.C. 552a(j)(2) and (k)(2). No exemptions are claimed for information obtained from an application or otherwise submitted by an applicant.

Dated: April 13, 2006.

**Maureen Cooney,**

*Acting Chief Privacy Officer.*

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