

If an applicant does not have a PSUR waiver in place for an approved application, the applicant may submit a waiver request under § 314.90(a) or § 600.90(a) to submit a PBRER instead of the PADER/PAER. The applicant should submit a request to FDA for each approved application for which a waiver is requested, and a single waiver request letter can include multiple applications. Waiver requests should be submitted to each of the application(s) in the request, and may be submitted electronically or by mail as described in the April 8, 2013, draft guidance. Each PBRER waiver request should include the following information:

1. The product name(s) and application number(s);
2. A brief description of the justification for the request;
3. The U.S. approval date for the product(s) and current reporting interval used;
4. The reporting interval of the last PADER/PAER submitted for the product(s);
5. The data lock point that will be used for each PBRER. If a data lock

point other than one aligned to the U.S. approval date is proposed, the applicant should describe how he/she will ensure that there are no gaps in reporting intervals (e.g., by submitting overlapping reports; submitting a one-time PADER/PAER to cover the gap period; or, if the gap is less than 2 months, extending the reporting interval of the final PADER/PAER to close the gap).

6. The frequency for submitting the PBRER, as described in section IV.C of the April 8, 2013, draft guidance.

7. The email address and telephone number for the individual who can provide additional information regarding the waiver request.

As explained earlier, existing regulations at §§ 314.90(a) or 600.90(a) permit applicants to request waivers of any postmarketing safety reporting requirement, and the information collections associated with such waiver requests generally are approved under OMB control numbers 0910-0001 and 0910-0308. FDA believes that the information submitted under numbers 1 to 4 and number 7 in the list in the

previous paragraph is information that is typical of any waiver request regarding postmarketing safety reporting and is accounted for in the existing approved collections of information for waiver requests and reports. Concerning numbers 5 and 6, FDA expects approximately 67 waiver requests to include the additional information for using a different data lock point and/or for using a different reporting frequency when submitting a PBRER. FDA expects approximately 29 applicants to make these submissions, and we estimate that the time for submitting the additional information described in the previous paragraph would be on average approximately 2 hours for each waiver request.

In the **Federal Register** of December 10, 2013 (78 FR 74151), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the additional burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Additional information and/or notifications for using a different data lock point and/or a different reporting frequency	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Applicants that have a PSUR waiver for an approved application	55	3.4	187	1	187
Applicants that do not have a PSUR waiver for an approved application	29	2.3	67	2	134
Total	321

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

Dated: May 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Committee on Organ Transplantation; Cancellation of Meeting

Name: Advisory Committee on Organ Transplantation.

Dates and Times: May 15, 2014, 10:00 a.m. to 4:00 p.m., Eastern Time.

Status: The meeting of the Advisory Committee on Organ Transplantation scheduled for May 15, 2014, is cancelled. This cancellation applies to

all sessions of the meeting. The meeting was announced in the **Federal Register** on April 22, 2014 (79 FR 22507).

For Further Information Contact:

Patricia Stroup, MBA, MPA, Office of the Associate Administrator, Healthcare Systems Bureau, Health Resources and Services Administration, 5600 Fishers Lane, Room 17W43, Rockville, Maryland 20857; telephone (301) 443-1127.

Dated: May 5, 2014.

Bahar Niakan,

Director, Division of Policy and Information Coordination.

[FR Doc. 2014-10739 Filed 5-8-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2014-0022]

Privacy Act of 1974; Computer Matching Program

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

OVERVIEW INFORMATION: Privacy Act of 1974; Computer Matching Program between the Department of Homeland Security, U.S. Citizenship and Immigration Services and the Massachusetts Division of Unemployment Assistance.

SUMMARY: This document provides notice of the existence of a computer matching program between the Department of Homeland Security, U.S.

Citizenship and Immigration Services and the Massachusetts Division of Unemployment Assistance, titled "Verification Division DHS-USCIS/MA-DUA."

SUPPLEMENTARY INFORMATION: The Department of Homeland Security, U.S. Citizenship and Immigration Services provides this notice in accordance with The Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100-503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101-508) (Privacy Act); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A-130, Appendix I, 65 FR 77677 (December 12, 2000).

Participating Agencies: The Department of Homeland Security, U.S. Citizenship and Immigration Services (DHS-USCIS) is the source agency and the Massachusetts Division of Unemployment Assistance (MA-DUA) is the recipient agency.

Purpose of the Match: This Computer Matching agreement allows DHS-USCIS to provide MA-DUA with electronic access to immigration status information contained within the DHS-USCIS Verification Information System (VIS). The immigration status information will enable MA-DUA to determine whether an applicant is eligible for benefits under the Unemployment Compensation (UC) program administered by MA-DUA.

Authority for Conducting the Matching Program: Section 121 of the Immigration Reform and Control Act (IRCA) of 1986, Public Law 99-603, as amended by the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA), requires DHS to establish a system for the verification of immigration status of alien applicants for, or recipients of, certain types of benefits and to make this system available to state agencies that administer such benefits. Section 121(c) of IRCA amends Section 1137 of the Social Security Act and certain other sections of law that pertain to Federal entitlement benefit programs to require state agencies administering these programs to use the DHS-USCIS verification system to make eligibility determinations in order to prevent the issuance of benefits to alien and naturalized/derived United States citizen applicants who are not entitled to program benefits because of their immigration status. The VIS database is

the DHS-USCIS system established and made available to MA-DUA and other covered agencies for use in making these eligibility determinations.

MA-DUA seeks access to the information contained in DHS-USCIS VIS database for the purpose of confirming the immigration status of alien applicants for, or recipients of, the benefits it administers, in order to discharge its obligation to conduct such verifications pursuant to Section 1137 of the Social Security Act, 42 U.S.C. 1320b-7, and to Mass. Gen. Laws ch. 151A, § 25(h).

Categories of Records and Individuals Covered: DHS-USCIS will provide the following to MA-DUA: Records in the DHS-USCIS VIS database containing information related to the status of aliens and other persons on whom DHS-USCIS has a record as an applicant, petitioner, or beneficiary. See DHS-USCIS-004 Systematic Alien Verification for Entitlements Program System of Records Notice, 77 FR 47415 (August 8, 2012).

MA-DUA will provide the following to DHS-USCIS: MA-DUA records pertaining to alien and naturalized/derived United States citizen applicants for, or recipients of entitlement benefit programs administered by the State.

MA-DUA will match the following records with DHS-USCIS records:

- Alien Registration Number
- 1-94 Number
- Last Name
- First Name
- Middle Name
- Date of Birth
- Nationality
- Social Security Number (SSN)

DHS-USCIS will match the following records with MA-DUA records:

- Alien Registration Number
- Last Name
- First Name
- Middle Name
- Date of Birth
- Country of Birth (not nationality)
- SSN (if available)
- Date of Entry
- Immigration Status Data
- Sponsorship Information (sponsor's full name, SSN, and address)

Inclusive Dates of the Matching Program: The inclusive dates of the matching program are from June 14, 2014, and continuing for 18 months through December 13, 2015. The matching program may be extended for up to an additional 12 months thereafter, if certain conditions are met.

Address for Receipt of Public Comments or Inquires: Individuals wishing to comment on this matching program or obtain additional

information about the program, including requesting a copy of the computer matching agreement between DHS-USCIS and MA-DUA, may contact:

For general questions please contact: Donald K. Hawkins, 202-272-8030, Privacy Officer, U.S. Citizenship and Immigration Services, Department of Homeland Security, 20 Massachusetts Avenue NW., Washington, DC 20529.

For privacy questions please contact: Karen L. Neuman (202-343-1717), Chief Privacy Officer, Privacy Office, Department of Homeland Security, Washington, DC 20528.

Dated: April 29, 2014.

Karen L. Neuman

Chief Privacy Officer, Department of Homeland Security.

[FR Doc. 2014-10594 Filed 5-8-14; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Office of the Secretary

[Docket No. DHS-2014-0025]

Privacy Act of 1974; Computer Matching Program

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: Notice.

Overview Information: Privacy Act of 1974; Computer Matching Program between the Department of Homeland Security, U.S. Citizenship and Immigration Services and the Texas Workforce Commission.

SUMMARY: This document provides notice of the existence of a computer matching program between the Department of Homeland Security, U.S. Citizenship and Immigration Services and the Texas Workforce Commission, titled "Verification Division DHS-USCIS/TWC."

SUPPLEMENTARY INFORMATION: The Department of Homeland Security, U.S. Citizenship and Immigration Services provides this notice in accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100-503) and the Computer Matching and Privacy Protection Amendments of 1990 (Pub. L. 101-508) (Privacy Act); Office of Management and Budget (OMB) Final Guidance Interpreting the Provisions of Public Law 100-503, the Computer Matching and Privacy Protection Act of 1988, 54 FR 25818 (June 19, 1989); and OMB Circular A-