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of the application(s) in the request, and may be submitted electronically or by mail as described in the April 8, 2013, draft guidance.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 The frequency for submitting the PBRER, as described in section IV.C of the April 8, 2013, draft guidance.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 0910–0001and 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.

[FR Doc. 2014–10658 Filed 5–8–14; 8:45 am]

BILLING CODE 4160–01–P

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]

BILLING CODE 4165–15–P

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.