free telephone number and email address, and FDA experience. Each report is expected to take 0.25 hours to complete and submit; therefore, total burden hours for this collection of information is estimated to be 200 hours (800 responses × 0.25 hours per response). The total burden hours for this collection have decreased by 50 hours (from 250 to 200) because the number of estimated respondents decreased from 1,000 to 400, and the annual responses are expected to drop from 1,000 to 800. Based on past submissions to FDA, the number of estimated annual respondents is expected to decrease from 1,000 to 400 and each respondent's number of submissions is expected to increase from 1 to 2 annually. Therefore, the number of responses is expected to decrease from 1,000 to 800 annually (400 respondents × 2 responses).

Dated: May 5, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–10657 Filed 5–8–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–1478]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Providing Waiver-Related Materials in Accordance With Draft Guidance for Industry on Providing Postmarket Periodic Safety Reports in the International Conference on Harmonisation E2C(R2) Format

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Fax written comments on the collection of information by June 9, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reporting in Accordance With International Conference on Harmonisation—Periodic Benefit Risk Evaluation Report (E2C(R2)) Guidance—(OMB Control Number 0910–NEW)

I. Background

The International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. In January 2012, the ICH Steering Committee agreed that the ''E2C(R2) Periodic Benefit-Risk Evaluation Report'' draft guidance (the draft PBRER guidance) should be made available for public comment. The PBRER is intended to provide a common standard for periodic reporting on approved drugs or biologics among the ICH regions. The harmonized PBRER is intended to promote a consistent approach to periodic postmarket safety reporting among the ICH regions and to enhance efficiency by reducing the number of reports generated for submission to the regulatory authorities.

The draft PBRER guidance revises an earlier version of this guidance issued in 1997 with an addendum issued in 2004. In the **Federal Register** of April 11, 2012 (77 FR 21782), FDA announced the availability of the draft PBRER guidance for public comment. FDA presented the comments received as part of the considerations by the E2C(R2) Expert Working Group for revisions of the guidance. A final version of the guidance was subsequently endorsed by the ICH on November 15, 2012, and published as the ICH harmonized tripartite guideline ''Periodic Benefit-Risk Evaluation Report (PBRER) E2C(R2)'' (the PBRER guidance), available at *http://www.ich.org/products/guidelines/efficacy/article/efficacy-guidelines.html.* FDA anticipates issuing final guidance on this topic that is consistent with the final ICH document, published November 2012, and thus is seeking PRA approval for information collections consistent with that document.

II. Voluntary Preparation of Periodic Safety Reports in Conformance With the ICH E2C(R2) PBRER Guidance, in Lieu of PADERs/PAERs Required Under 21 CFR 314.80(c)(2) and 600.80(c)(2)

FDA currently has OMB approval for the required submission of periodic adverse drug experience reports (PADER) for drugs subject to a new drug application (NDA) or an abbreviated new drug application (ANDA) (§ 314.80(c)(2) (21 CFR 314.80(c)(2)); OMB control number 0910–0230), and for the required submission of periodic adverse experience reports (PAER) for drugs subject to a biologics license application (BLA) (§ 600.80(c)(2) (21 CFR 600.80(c)(2)); OMB control number 0910–0308). Such reports include, for the reporting interval, reports of serious, expected adverse experiences and all non-serious adverse experiences and an index of these reports, a narrative summary and analysis of adverse experiences, an analysis of the 15-day Alert reports submitted during the reporting interval, and a history of actions taken because of adverse experiences. Applicants must submit each PADER/PAER to FDA quarterly for the first 3 years after the product is approved by FDA and annually thereafter. As described in the supporting documentation under OMB control numbers 0910–0230 and 0910–0308, FDA currently has OMB approval for approximately 60 hours for the preparation and submission of each PADER under § 314.80(c)(2) and 28 hours for the preparation and submission of each PAER under § 600.80(c)(2).

There is considerable overlap in the information required under §§ 314.80(c)(2) and 600.80(c)(2) and the information requested in a periodic safety report using the ICH E2C(R2) PBRER format. As a result, and as discussed further in this document, FDA, in the **Federal Register** of April 8, 2013 (78 FR 20926), announced the availability of a draft guidance to indicate its willingness to accept postmarket periodic safety reports using the ICH PBRER format in lieu of the

specific reports described in FDA regulations. (As described further in this document, the April 2013 draft guidance also addresses waiver-related information that should be submitted to FDA by companies who wish to exercise this alternative reporting.)

Companies who submit periodic reports on the same drug to multiple regulators, including not only the United States, but, also the European Union, Japan, and regulators in other countries who have elected to adopt the ICH standards, may find it in their interest to prepare a single PBRER, rather than preparing multiple types of reports for multiple regulators. Companies who choose to submit a PBRER to FDA would include some information beyond that required by FDA regulations, including worldwide marketing approval status; estimated exposure and use patterns; information from clinical trials, non-interventional studies, non-clinical data, and literature; benefit evaluation, and benefit-risk analysis for approved indications, and should use a particular format described in the draft PBRER guidance.

FDA is not proposing to require submission of the PBRER; applicants subject to periodic safety reporting requirements under FDA regulations could choose to continue to submit the reports as specified in those regulations, and would be permitted to alternate between submission of reports in the PBRER format and submission of reports as specified in FDA regulations with an approved waiver. Based on FDA's experience with submission of periodic safety reports under previous ICH periodic reporting guidance, FDA believes that applicants would elect to submit the PBRER to FDA only in cases where they are also submitting that report to other regulatory authorities, some of which have underlying legal requirements that closely parallel the elements of the PBRER. For this reason, FDA believes that the additional burden associated with preparation of a PBRER in lieu of existing PADERs/PAERs is not attributable to the proposed collection of information by FDA, but rather is a ''usual and customary'' expenditure of time, effort, and financial resources that would be ''incurred by persons in the normal course of their activities,'' and thus is excluded from the calculation of burden under the PRA (5 CFR 1320.5(b)(2).) Cf. 5 CFR 1320.5(b)(3) (permitting exclusion from Federal burden of burden incurred in complying with an information collection that is also conducted by a State or local government if the State or local requirement would be imposed even in the absence of a Federal requirement).

We therefore believe that the existing estimate of burden for submission of periodic safety reports, approved under OMB control numbers 0910–0230 and 0910–0308, would be unchanged by this proposed collection, which would permit, but not require, the substitution of a PBRER for the periodic safety report otherwise required. We request comment on the assumption that all PBRERs submitted to FDA would be prepared in any event to submit to other jurisdictions, or alternatively, on the number of PBRERs that applicants will choose to prepare solely for submission to FDA, and the estimated burden for submitting such a report.

III. Materials Related to Waivers Permitting Submission of a PBRER To Satisfy the Periodic Safety Reporting Requirements in §§ 314.80(c)(2) and 600.80(c)(2)

Because FDA regulations in §§ 314.80(c)(2) and 600.80(c)(2) include specific requirements for periodic safety reports, in order for an applicant to submit an alternative report, such as the PBRER, for a given product, FDA must grant a waiver. Existing regulations permit applicants to request waivers of any postmarketing safety reporting requirement, and the information collections associated with such waiver requests generally are approved under existing control numbers. (See § 314.90(a), waivers for drugs subject to NDAs and ANDAs (approved under OMB control number 0910–0001); and § 600.90(a), waivers for products subject to BLAs (approved under OMB control number 0910–0308).)

In the **Federal Register** of April 8, 2013, FDA announced the availability of a draft guidance entitled ''Providing Postmarket Periodic Safety Reports in the ICH E2C(R2) Format'', which indicates that FDA will be prepared to grant waivers to enable submission of the PBRER in the United States in place of a PADER required under § 314.80(c)(2) or in place of a PAER required under § 600.80(c)(2). The draft guidance both explains conditions under which applicants that have previously received waivers to submit reporting information in the format of the previous ICH guidance would be permitted to apply those existing waivers to the submission of PBRERs, and also advises how applicants that have not previously obtained a waiver may submit waiver requests to submit the PBRER. This **Federal Register** notice solicits comment on certain information collections proposed in the April 8, 2013, draft guidance that are related to waivers specifically to enable the submission of PBRERs, and that are not already addressed under approved control numbers covering waiver submissions and periodic safety reports generally.

FDA has previously granted waiver requests, submitted under §§ 314.90(a) and 600.90(a), that allow applicants to prepare and submit reports using the periodic safety update report (PSUR) format described in the 1997 and 2004 ICH E2C guidance. In accordance with the recommendations of the April 8, 2013, draft guidance, if an applicant already has a PSUR waiver in place for a given approved application, FDA will consider the existing PSUR waiver to allow the applicant to submit a PBRER instead of a PSUR because the PBRER replaces the PSUR for postmarketing periodic safety reporting for that application. The applicant would not need to submit a new waiver request unless the applicant wishes to change the frequency of reporting. FDA will consider requests to be waived of the quarterly reporting requirement but will not waive applicants of the annual reporting requirement.

If an applicant submits a PBRER in place of the PSUR and uses a different data lock point, the applicant should submit overlapping reports or submit a one-time PADER/PAER in order to cover the gap in reporting intervals. The applicant should submit notification to the application(s), indicating the change in data lock point and should include a description of the measures taken to ensure that there are no resulting gaps in reporting.

If an applicant submits a PBRER in place of the PSUR and uses a different reporting frequency for the PBRER than was used for the PSUR, the continued validity of the waiver will be conditioned on the submission of a PADER/PAER as needed to fulfill the reporting frequency requirement under FDA regulations. The applicant should submit a notification to the application(s), describing this change and the measures taken to ensure that the periodicity requirements are being met.

FDA expects approximately 187 waiver requests and notifications to include the additional information described previously in this document for using a different data lock point and/or for using a different reporting frequency when submitting a PBRER. FDA expects approximately 55 applicants to make these submissions, and we estimate that the time for submitting the additional information described previously would be on average approximately 1 hour for each waiver request or notification.

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.