trial designs that may provide evidence of efficacy to support drug approval.

The Agency encourages individuals, patient advocates, industry, consumer groups, health care professionals, researchers, and other interested persons to attend this public workshop.

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. Transcripts will also be available on the Internet at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* approximately 45 days after the workshop.

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19257 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0334]

Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule entitled ''Postmarketing Safety Reports for Human Drug and Biological Products; Electronic Submission Requirements'' that appeared in the **Federal Register** of June 10, 2014 (79 FR 33072). The document amended FDA's postmarketing safety reporting regulations for human drug and biological products to require that persons subject to mandatory reporting requirements submit safety reports in an electronic format that FDA can process, review, and archive. The document was published with incorrect information regarding the availability of the International Conference on Harmonization's (ICH) data elements for postmarketing safety reports. The document also published with an incorrect statement regarding the impact of the final rule on small entities. This document corrects those errors.

FOR FURTHER INFORMATION CONTACT: Jean Chung, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4466, Silver Spring, MD 20993–0002, 301–796–1874; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7268, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of June 10, 2014, in FR Doc. 2014–13480, the following corrections are made:

1. On page 33074, in the first column, under ''Introduction'', footnote 6 is corrected to read: ''ICH data elements for postmarketing safety reports are provided in the guidance for industry entitled 'E2B Electronic Transmission of Individual Case Safety Reports Implementation Guide—Data Elements and Message Specification,' available at *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm.''*

2. On page 33084, in the second column, under ''Analysis of Impacts'', the first full sentence is corrected to read: ''Because the average small entity submits few safety reports and the Agency's Web-based system for submitting reports electronically will require little additional cost per report, the Agency certifies that this final rule will not have a significant economic impact on a substantial number of small entities.''

Dated: August 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–19255 Filed 8–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than September 15, 2014.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Federal Tort Claims Act (FTCA) Free Clinic Application OMB No. 0915–0293—Revision.

Abstract: Under 42 U.S.C. 233(o) and Program Assistance Letter (PAL) 2014–04, ''Calendar Year 2015 Federal Tort Claims Act (FTCA) Deeming Application for Free Clinics,'' free clinics are required to submit annual applications for deeming of qualified health care professionals, board members, officers, and contractors for purposes of FTCA medical malpractice coverage for negligent acts and omissions that arise from the performance of medical, surgical, dental, or related functions within the scope of the covered individual's deemed employment. HRSA proposes modifying the application forms to reflect changes to eligible personnel made by section 10608 of the Affordable Care Act, which extended FTCA medical malpractice liability protection to free clinic board members, officers, employees, and contractors. Additionally, HRSA proposes upgrading the application to provide for electronic submissions. Specifically, the modifications include: (1) Inclusion of board members, officers, employees, and contractors into one comprehensive application that also includes volunteer health care professionals and (2) a fully electronic application that can be submitted via HRSA's web-based application system, the Electronic Handbooks (EHBs). It is anticipated that

these modifications will decrease the time and effort required to complete the current OMB approved FTCA application forms.

Need and Proposed Use of the Information: Deemed status for FTCA medical malpractice coverage requires HRSA approval of an application for deeming of certain eligible individuals from a sponsoring free clinic. The FTCA Free Clinic deeming application is an electronic application submitted to HRSA through the EHBs as part of the process of deeming qualified health care professionals, board members, officers, and individual contractors. Sponsoring clinics are required to submit a completed electronic application in addition to other required documents as required by section 224(o) of the Public Health Service Act (42 U.S.C. 233(o)). Applications are reviewed by program staff before a deeming determination is made.

Likely Respondents: Respondents include nonprofit private entities that meet the statutory and programmatic requirements as stated in section 224(o) of the Public Health Service Act (42 U.S.C. 233(o)) and implementing HRSA policy guidance.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
FTCA Free Clinics Program Application	227	1	227	2	681
Total	227	1	227	2	681

Dated: August 8, 2014.

Jackie Painter,

Acting Director, Division of Policy and Information Coordination.

[FR Doc. 2014–19219 Filed 8–13–14; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995), the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than October 14, 2014.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 10–29, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Be The Match® Patient Services Survey OMB No. 0915–0212—Revision.

Abstract: National Marrow Donor Program®/Be The Match® is dedicated to helping patients and families get the support and information they need to learn about their disease and treatment options, prepare for transplant, and thrive after transplant. The information and resources provided are intended to help navigate the bone marrow or cord blood transplant (transplant) process. Participant feedback is essential to understand the needs for transplant support services and educational information across a diverse population. This information will be used to determine helpfulness of existing services and resources. Feedback is also used to identify areas for improvement and develop future programs.

Need and Proposed Use of the Information: Barriers to access to bone marrow or cord blood transplant (transplant) related care and educational information are multi-factorial. Feedback from participants is essential to better understand the changing needs for services and information as well as to demonstrate the effectiveness of existing services. The primary use for information gathered through the survey is to determine helpfulness of participants' initial contact with Be The Match® Patient Services Coordinators (PSC) and to identify areas for improvement in the delivery of services.

The survey will include items to measure: (1) Reason for contacting Be The Match®; (2) if the PSC was able to answer questions and were easy to understand; (3) if the contact helped the participant to feel better prepared to discuss transplant with their care team; (4) increase in awareness of available resources; (5) timeliness of response; and (6) overall satisfaction. Stakeholders utilize this evaluation data to make program and resource allocation decisions.

Likely Respondents: Respondents will include all patients, caregivers and family members who have contact with Be The Match® Patient Services Coordinators via phone or email for transplant navigation services and support (advocacy). The decision to survey all participants was made based