thinking of FDA on ''Content of Premarket Submissions for Device Software Functions.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics.* Persons unable to download an electronic copy of ''Content of Premarket Submissions for Device Software Functions'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number GUI00000337 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in the following FDA regulations, guidance, and forms have been approved by OMB as listed in the following table:

21 CFR part; guidance; or FDA form	Topic	OMB control No.
807, subpart E	Premarket notification	0910–0120
814, subparts A through E	Premarket approval	0910–0231
814, subpart H	Humanitarian Device Exemption	0910–0332
812	Investigational Device Exemption	0910–0078
860, subpart D	De Novo classification process	0910–0844
601; Form FDA 356h	Biologics License; Application to Market a New or Abbreviated New Drug or Biologic for Human Use—Form FDA 356h.	0910–0338
''Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program''.	Q-submissions	0910–0756
800, 801, and 809	Medical Device Labeling Regulations	0910–0485
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910–0073

Dated: June 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–12723 Filed 6–13–23; 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; Be The Match® Patient Support Center Survey—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 14, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Samantha Miller, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Be The Match® Patient Support Center Survey

OMB No. 0906–0004—Revision

Abstract: The C.W. Bill Young Cell Transplantation Program was established by the Stem Cell Therapeutic and Research Act of 2005 (Pub. L. 109–129) and was reauthorized in 2010 (Pub. L. 111–264), 2015 (Pub. L. 114–104) and again in 2021 (Pub. L. 117–15). The C.W. Bill Young Cell Transplantation Program Office of Patient Advocacy (OPA) is operated by the National Marrow Donor Program® (NMDP). Through OPA, NMDP provides navigation services, education resources, and support to people in need of or who have received an allogeneic hematopoietic cell transplant (allo-HCT). As the contractor for OPA, NMDP is required to conduct surveys to evaluate patient satisfaction with the services provided. As such, NMDP will elicit feedback from HCT patients, caregivers, and family members who had contact with the NMDP/Be The Match® Patient Support Center (PSC) for service and support. The survey is administered through a web-based system. In addition to questions that measure satisfaction, the survey also includes demographic questions to determine the representativeness of findings.

A 60-day notice was published in the **Federal Register** on March 2, 2023, vol. 88, No. 41; pp. 13130–31. There were no public comments.

Need and Proposed Use of the Information: HCT is a complex medical

procedure that requires significant support before, during, and after the procedure. Many patients experience barriers that impede access to HCT. Barriers to HCT-related care and educational information are multi-factorial. The NMDP/Be The Match PSC offers many programs and services to support patients, caregivers, and family members throughout their HCT journey. Feedback from recipients of NMDP services is essential to 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 the helpfulness of participants' initial contact with the PSC patient navigators and to identify areas for improvement in the delivery of services. Patient navigators are trained lay or licensed clinical patient navigators, who respond to requests for information and support. Program managers and NMDP leadership use this evaluation data to share patients' experiences as well as make program and resource allocation decisions.

Web-based surveys will be administered to all participants (patients, caregivers, and family members) who have contact with the PSC. All participants for whom an email address is known will be invited to complete the survey online. Survey respondents will be notified via email invitation and in the survey instructions that participation is voluntary, and responses will be kept confidential. A follow-up invitation will be sent within 2 weeks to non-respondents.

The survey will include these items to measure: (1) their experience, (2) if the contact helped the participant feel more confident in coping with treatment, (3) if the contact helped the participant feel more hopeful, (4) if the contact helped the participant feel less alone, (5) increased awareness of available resources, (6) if the contact helped the participant feel more informed about treatment options, (7) if their questions were answered, and (8) types of challenges faced by the participant. The survey data will be analyzed quarterly and annually, and results will be shared with program managers. Feedback indicating a need for improvement will be reviewed by program managers biannually and implementation of resulting program changes or additions will be documented.

Likely Respondents: Respondents will include all patients, caregivers, and family members who have contact with the Patient Support Center via phone or email for HCT navigation services and support (advocacy). The decision to survey all participants was made based on the historically low response rate (~20 percent) to this survey due to patients' frequent transitions in health status as well as transfer between home and the hospital for initial treatment and care for complications. Participants will receive the survey once in a 1-year cycle. If a participant contacts the Patient Support Center one or more years after the initial contact, they will receive a second survey. This is because it is anticipated that the participants' needs will likely change during the time lapse.

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
Be The Match® Patient Support Center Survey	900	1	900	0.17	153
Total	900	1	900	0.17	153

The total respondent burden for the customer satisfaction surveys is estimated to be 153 hours. HRSA expects a total of 900 respondents to complete the Be The Match® Patient Support Center Survey.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–12666 Filed 6–13–23; 8:45 am]

BILLING CODE 4165–15–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; Data System for Organ Procurement and Transplantation Network, OMB No. 0915–0157—Revision

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: In compliance with of the Paperwork Reduction Act of 1995, HRSA 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. OMB may act on HRSA's ICR only after the 30-day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than July 14, 2023.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for