and discussion of CDC-funded public health preparedness and response centers including the Centers for Public Health Preparedness and Response (CPHPs, 2004–2010), Preparedness and Response Learning Centers (PERLCs, 2010–2015), and Preparedness and Response Research Centers (PERRCs, 2008–2013). CDC seeks public input on opportunities and challenges for designing and implementing a network of regional centers for public health preparedness and response consistent with section 319F of the Public Health Service Act (42 U.S.C. 247d-6), as amended by the Consolidated Appropriations Act, 2023, sec. 2231 (*https://www.congress.gov/bill/117th-congress/house-bill/2617?r=1&s=3*).

How town hall meeting input will be used: As appropriate, future funding opportunities will use input from town hall participants, including the following: (1) examples of past successful activities and strategies; (2) potential partnership opportunities between CDC and awardees; and (3) types of technical assistance that would benefit funded projects.

Matters to be considered: The agenda will include presentations and discussions on three topic areas: (1) strengths and limitations of past CPHP, PERLC, PERRC and similar programs; (2) new program priorities as directed by sec. 2231 of the Consolidated Appropriations Act, 2023; and (3) discussion of how best to meet state, territorial, local, and tribal public health preparedness and response needs in the design, implementation, and coordination of regional centers under the new Consolidated Appropriations Act, 2023, sec. 2231 language. There will be prepared presentations, discussions among presenters and panelists, and a period for questions and public comments. Agenda items are subject to change as priorities dictate.

Specific questions for the public to consider: The goal of the new Consolidated Appropriations Act, 2023, sec. 2231 language is to implement a network of regional centers for public health preparedness and response for the purpose of increasing uptake of evidence-based preparedness and response programs. What have we learned from past CPHP, PERLC, PERRC and similar programs that will increase opportunities to reach this goal? How might CDC and funded regional centers leverage other initiatives and partners to enhance the evidence base and its implementation? Section 319F requires award recipients to coordinate with state, local, and tribal health departments and officials, health care facilities, and health care coalitions. Are there other entities that could be engaged at the regional level that members of the public recommend be included or informed about this work? What are the greatest public health preparedness and response needs that should be addressed to support the goals of section 319F in the regions?

Background: CDC's Office of Readiness and Response is hosting the town hall meeting with invited speakers representing public health and healthcare preparedness partners nationwide including from academia, government, and national associations to address new authorization language requiring the establishment and maintenance of a network of regional centers for public health preparedness and response.

CDC commissioned the National Academies of Sciences, Engineering, and Medicine to address a longstanding need for a comprehensive, systematic review and grading of public health emergency preparedness and response (PHEPR) evidence for practice. The resulting 2020 consensus study report, *Evidence-Based Practice for Public Health Emergency Preparedness and Response* (*https://doi.org/10.17226/25650*), reviews the status of evidence on PHEPR practices and the improvements needed to advance the field and strengthen the PHEPR system. The report provides recommendations seeking to strengthen PHEPR research and support effective and sound evidence-based PHEPR practice.

Section 2231 of the Consolidated Appropriations Act, 2023 amended section 319F to incorporate new requirements and priorities for establishing or maintaining a network of Centers for Public Health Preparedness and Response, including coordination of activities with partners and implementation of evidence-informed or evidence-based PHEPR practices.

The discussion and feedback generated during the town hall will assist CDC in developing program guidance related to workplan development and overall structure of regional coordinating bodies. Ultimately, feedback will be used to inform the establishment and maintenance of a network of regional centers. Participants may provide individual feedback or perspectives. CDC is not seeking consensus advice or recommendations from participants.

Dated: June 9, 2023.

Tiffany Brown,

Executive Secretary, Centers for Disease Control and Prevention.

[FR Doc. 2023–12741 Filed 6–13–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0775]

Content of Premarket Submissions for Device Software Functions; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled ''Content of Premarket Submissions for Device Software Functions.'' This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of safety and effectiveness of device software functions, which are functions that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This document replaces FDA's ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'' issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

DATES: The announcement of the guidance is published in the **Federal Register** on June 14, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your

comments, that information will be posted on *https://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2021–D–0775 for ''Content of Premarket Submissions for Device Software Functions.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

• Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

An electronic copy of the guidance document is available for download from the internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Content of Premarket Submissions for Device Software Functions'' to the Office of Policy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Brendan O'Leary, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5530, Silver Spring, MD 20993–0002, 301–796–6898; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993, 240–402–7911; Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Hillandale Bldg., 4th Floor, Silver Spring, MD 20993–0002, 301–796–3400; or John Weiner, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5130 HFG–3, Silver Spring, MD 20993–0002, 301–796–8941.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this guidance is to describe FDA's thinking on the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions. This thinking recognizes changes to the FD&C Act made by the 21st Century Cures Act (Cures Act), which amended section 520 of the FD&C Act (21 U.S.C. 360j) and excludes certain software functions from the device definition. It also considers the rapidly evolving nature of digital health and recent FDA recognized consensus standards related to software.

The recommendations in this guidance are intended to facilitate FDA's premarket review. This guidance describes information that would be typically generated and documented during software development, verification, and design validation. The least burdensome approach was applied to identify the minimum amount of information that, based on our experience, would generally be needed to support a premarket submission for a device that uses software. During premarket review, FDA may request additional information that is needed to evaluate the submission.

This document replaces FDA's ''Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices'' issued on May 11, 2005, and updates FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions.

A notice of availability of the draft guidance appeared in the **Federal Register** of November 4, 2021 (86 FR 60838). FDA considered comments received and revised the guidance as appropriate in response to the comments, including edits to clarify FDA's risk-based approach to determining a device's Documentation Level (including an expanded Appendix of examples that illustrate application of the Documentation Level risk-based approach) as well as edits to clarify the recommended documentation that should be included within a premarket submission. The guidance also clarifies that the recommendations generally apply to the device constituent part of a combination product when the device constituent part includes a device software function, including combination products assigned to FDA's Center for Drug Evaluation and Research (CDER) or Center for Biologics Evaluation and Research (CBER) regulated under drug or biological product market submission types. FDA also edited the document to further clarify the recommended utilization of FDA-recognized versions of consensus standards, where appropriate, within a premarket submission.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current

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