Total Supplement Award Amount: $490,698 in FY 2022.

Award Type: Cooperative Agreement Supplement.

Statutory Authority: This program is authorized under Section 317 of the Public Health Service Act (42 U.S.C. 247(b–4)); Consolidated and Further Continuing Appropriations Act, 2015, Public Law 113–235 (Dec. 16, 2014).

Basis for Award: The Amputee Coalition of America, Inc. is currently funded to carry out the objectives of this program, entitled The *National Limb Loss Resource Center* for the period of April 1, 2019, through March 29, 2024. Almost 2 million Americans have experienced amputations or were born with limb difference and another 28 million people in our country are at risk for amputation. The supplement will enable the grantee to carry their work even further, serving more people living with limb loss and/or limb differences and providing even more comprehensive training and technical assistance in the development of long-term supportive services. The additional funding will not be used to begin new projects or activities. The NLLRC will enhance and expand currently funded activities such as conducting national outreach for the development and dissemination of patient education materials, programs, and services; providing technical support and assistance to community based limb loss support groups; and raising awareness about the limb loss and limb differences communities.

Establishing an entirely new grant project at this time would be potentially disruptive to the current work already well under way. More importantly, the people living with limb loss and limb differences currently being served by this program could be negatively impacted by a service disruption, thus posing the risk of not being able to find the right resources that could negatively impact on health and wellbeing. If this supplement were not provided, the project would be less able to address the significant unmet needs of additional limb loss survivors. Similarly, the project would be unable to expand its current technical assistance and training efforts in NLLRC concepts and approaches, let alone reach beyond traditional providers of services to this population to train more ''mainstream'' providers of disability services.

Date: May 27, 2022.

Alison Barkoff,

Acting Administrator and Assistant Secretary for Aging.

[FR Doc. 2022–12205 Filed 6–6–22; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–D–1138]

Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised); Withdrawal of Guidance

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notice; withdrawal.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the withdrawal of the guidance document entitled ''Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised),'' which was issued in June 2020 (and updated December 2020). FDA is withdrawing this guidance document in recognition that the conditions that created the need for these policies have evolved, such that these policies are no longer needed.

DATES: The withdrawal date is July 7, 2022.

FOR FURTHER INFORMATION CONTACT: Joshua Nipper, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2438, Silver Spring, MD 20993–0002, 301–796–5640, *Joshua.Nipper@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

As part of FDA's commitment to providing timely guidance to support continuity and response efforts to the Coronavirus Disease 2019 (COVID–19) [1] pandemic, in June 2020, the Agency published this guidance document (June 23, 2020 at 85 FR 34638) and updated it in December 2020, to recognize that the COVID–19 public health emergency was affecting the public health in numerous direct and indirect ways, including device development programs.[2] This guidance document answered frequently asked questions and implemented temporary policies to reduce industry burden.

FDA has continually assessed the needs and circumstances related to these temporary policies, and as relevant needs and circumstances evolved, the Agency made updates and modifications to these temporary policies. FDA has determined that the needs and circumstances related to the temporary policies described in the guidance document have evolved, such that they are no longer needed, and the guidance document should be withdrawn. In weighing the current burden to industry and the Agency relating to the COVID–19 response efforts with the need to ensure patients have timely access to new devices, FDA is withdrawing this guidance document. Below is a brief description of the guidance document and temporary policies that will be withdrawn:

The guidance articulated FDA's policy that for marketing submissions and applications on hold, FDA did not intend to consider a submission or application to be withdrawn for an additional 180 days beyond the relevant response date. Returning to pre-pandemic policies for marketing submissions and applications placed on hold after the withdrawal of this guidance means FDA will generally consider the submission or application to be withdrawn if the submitter or applicant does not provide a complete response to major deficiency letters for Premarket Approval Applications (PMAs) (original and supplements) [3] and Humanitarian Device Exemption (HDE) applications (original and supplements) [4] within 360 days or to additional information letters for 510(k) [5] and De Novo requests [6] within

[1] The virus has been named ''SARS–CoV–2'' and the disease it causes has been named ''Coronavirus Disease 2019'' (COVID–19).

[2] The term ''device(s)'' in this document refers to devices regulated by the Center for Devices and Radiological Health (CDRH) as well as devices regulated by the Center for Biologics Evaluation and Research (CBER), including devices regulated as biological products under section 351 of the Public Health Service (PHS) Act.

[3] For more information, please see the FDA guidance document entitled ''FDA and Industry Actions on Premarket Approval Applications (PMAs): Effect on FDA Review Clock and Goals'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-approval-applications-pmas-effect-fda-review-clock-and-goals*).

[4] For more information, please see the FDA guidance document entitled ''Humanitarian Device Exemption (HDE) Program'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/humanitarian-device-exemption-hde-program*).

[5] For more information, please see the FDA guidance document entitled ''FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals'' (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-and-industry-actions-premarket-notification-510k-submissions-effect-fda-review-clock-and-goals*).

[6] For more information, please see the FDA guidance document entitled ''FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals'' (*https://www.fda.gov/regulatory-information/search-fda-*

Continued

180 days, consistent with preexisting guidance.

When the COVID–19 public health emergency began, FDA understood that applicants may face challenges affecting their ability to meet their applicable response date for submissions placed on hold. FDA also recognized our potential difficulty in processing a high volume of individual extension requests on a timely basis. To alleviate these concerns, the guidance document articulated that FDA did not intend to consider an application or submission to be withdrawn for an additional 180 days beyond the relevant response date, regardless of whether the applicant submitted an extension request.

By weighing the current burdens on industry with FDA's interest in patients receiving timely access to new devices, FDA has determined it is in the interest of the public health to return to pre-pandemic policies regarding hold times. Reverting to policies regarding hold times described in the preexisting guidance documents should facilitate more timely premarket review of innovative and potentially lifesaving devices. In addition, closing out files that have been abandoned in a timelier manner allows for better management of the device review program. The Agency acknowledges that the circumstances giving rise to the public health emergency declaration for the COVID–19 pandemic continue to exist. However, the conditions that created the need for these policies have evolved, such that these policies are no longer needed, and it is in the best interest of patients and providers to reinstitute the original hold times to ensure patients have timely access to advanced technologies, diagnostics, and therapeutics without unnecessary delay.

The guidance document also discussed FDA's ability to host advisory committee meetings virtually and FDA's intention to work with relevant stakeholders to host all advisory committee meetings virtually. In returning to pre-pandemic policies, FDA will assess the appropriate venue for advisory committee meetings, keeping in mind FDA's successful implementation of virtual advisory committee meetings. Consistent with existing policy, the venue will be announced via the **Federal Register**.

Therefore, after careful review of current Agency processes, industry practices with regard to resolving submission deficiencies, and comments submitted to the public docket associated with the guidance, FDA is withdrawing the ''Effects of the COVID–19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices—Questions and Answers (Revised)'' guidance in its entirety.

II. Withdrawal Date

The withdrawal date for the guidance document discussed in this document is July 7, 2022. For submissions or applications that receive a major deficiency letter for PMA and HDE applications or additional information letters for 510(k) and De Novo requests prior to or on the guidance withdrawal date, FDA does not intend to consider the submission or application to be withdrawn for an additional 180 days beyond the relevant response date. For submissions or applications that receive a major deficiency letter or additional information letter after the guidance withdrawal date, FDA will generally consider the application or submission to be withdrawn if a complete response is not received by the relevant response date identified in that letter.

Authority: 21 U.S.C. 371(h).

Dated: June 1, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–12176 Filed 6–3–22; 8:45 am]

BILLING CODE 4164–01–P

guidance-documents/fda-and-industry-actions-de-novo-classification-requests-effect-fda-review-clock-and-goals).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request; The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—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 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. 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 7, 2022.

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 acting HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–9094.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: The Stem Cell Therapeutic Outcomes Database OMB No. 0915–0310—Revision.

Abstract: The Stem Cell Therapeutic and Research Act of 2005, Public Law (Pub. L.) 109–129, as amended by the TRANSPLANT Act of 2021, Public Law 117–15 (the Act), provides for the collection and maintenance of human blood stem cells for the treatment of patients and research. The Act requires the Secretary to contract for the establishment and maintenance of information related to patients who have received stem cell therapeutic products and to do so using an electronic format. HRSA has established the Stem Cell Therapeutic Outcomes Database (SCTOD), one component of the C.W. Bill Young Cell Transplantation Program (Program), which necessitates certain electronic record keeping and reporting requirements to perform the functions related to hematopoietic stem cell transplantation (HCT) under contract to HHS. Data is collected from transplant centers by the Center for International Blood and Marrow Transplant Research and is used for ongoing analysis of transplant outcomes to improve the treatment, survival, and quality of life for patients who may benefit from cellular therapies. Over time, there is an expected increase in the information reported as the number of transplants performed annually increases, and survivorship after transplantation improves. Similarly, because of ongoing rapid evolution in transplant indications, methods to establish diagnoses, disease prognostic factors, treatments provided before HCT, methods to determine donor matching, and transplantation techniques, the Program anticipates frequent incremental changes in information