intended to give CBER regulatory project managers and/or reviewers an opportunity to tour biotechnology manufacturing facilities developing cellular and gene therapy products, and to exchange regulatory experiences with their industry counterparts. With this program, CBER intends to enhance review efficiency and quality by providing CBER staff with a better understanding of the biotechnology manufacturing industry and its operations. The purpose of this notice is to invite companies developing cellular and gene therapy products interested in participating in this program to contact OTP for more information.

DATES: Companies may send proposed agendas to the Agency by August 14, 2024.

FOR FURTHER INFORMATION CONTACT: Lori Tull, Office of Review Management and Regulatory Review, Office of Therapeutic Products, Center for Biologics Evaluation and Research, Food and Drug Administration, 240–402–8361, *Lori.Tull@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Under section 351 of the Public Health Service Act (PHS Act), FDA is authorized to license biological products if they have been demonstrated to be ''safe, pure, and potent.'' CBER is one of two Centers at FDA that regulates biological products for human use under applicable statutory provisions of the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 3033 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255), was signed into law on December 13, 2016, and amended section 506 of the FD&C Act to specifically address the expedited development and review of certain regenerative medicine therapies, including cell therapies, therapeutic tissue engineering products, and human cell and tissue products.

An important part of CBER's commitment to make safe and effective biological products available to all Americans is optimizing the efficiency and quality of the biologics review process. To support this goal, CBER has initiated various training and development programs to promote high performance in its regulatory project management and review staff. OTP seeks to enhance review efficiency and review quality by providing staff with a better understanding of the biotechnology industry and its operations. To this end, CBER/OTP is offering regulatory project managers and reviewers the opportunity to tour biotechnology manufacturing facilities. The goals are to provide the following: (1) firsthand exposure to industry's product development processes and (2) a venue for sharing information about project management best practices (but not product-specific information) with industry representatives.

II. The Interactive Site Tours Program

In this program, which may last a few days, a small group of OTP regulatory project managers and/or reviewers, potentially also including senior level staff, can observe operations of biologics manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to provide an avenue for open dialogue between CBER/OTP staff and industry representatives. During the Interactive Site Tours Program, regulatory project managers and reviewers may also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both OTP staff and industry. The primary objective of the daily workshops is to understand the team approach to biological product development, including discovery, nonclinical and clinical evaluation, postmarketing activities, and regulatory submission operations. The overall benefit to regulatory project managers and reviewers will be exposure to project management, team techniques, and processes employed by the biotechnology industry. By participating in this program, the regulatory project managers and reviewers will gain a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Interactive Site Tours Program will be the responsibility of OTP; therefore, selection of facility tour sites will be based on the availability of funds and resources for the program. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective locations. Firm participation in the program is limited to companies developing cellular and/or gene therapy products. Firms that want to learn more about this opportunity or that are interested in offering a site tour should respond by sending a proposed agenda via email directly to Lori Tull (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: July 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15351 Filed 7–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–3165]

Takeda Pharmaceuticals U.S.A., Inc.; Withdrawal of Approval of New Drug Application for EXKIVITY (Mobocertinib Succinate) Capsule, Equivalent to 40 Milligrams Base

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is withdrawing approval of the new drug application (NDA) for EXKIVITY (mobocertinib succinate) capsule, equivalent to (EQ) 40 milligrams (mg) base, held by Takeda Pharmaceuticals U.S.A., Inc., 95 Hayden Ave., Lexington, MA 02421 (Takeda). Takeda has voluntarily requested that FDA withdraw approval of this application and has waived its opportunity for a hearing.

DATES: Approval is withdrawn as of July 15, 2024.

FOR FURTHER INFORMATION CONTACT: Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, *Kimberly.Lehrfeld@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: On September 15, 2021, FDA approved NDA 215310 for EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy (EGFR exon 20 insertion-mutated NSCLC), under the Agency's accelerated approval regulations, 21 CFR part 314, subpart H. The accelerated approval of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, for EGFR exon 20 insertion-mutated NSCLC included a required postmarketing trial intended to verify the clinical benefit of EXKIVITY.

On October 19, 2023, FDA met with Takeda to discuss the voluntary withdrawal of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, according to § 314.150(d) (21 CFR 314.150(d)). On October 25, 2023, FDA recommended the applicant voluntarily request withdrawal of approval of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, for EGFR exon 20 insertion-mutated NSCLC according to § 314.150(d) because the postmarketing trial did not verify clinical benefit. FDA also requested Takeda waive its opportunity for a hearing.

On March 15, 2024, Takeda submitted a letter asking FDA to withdraw approval of NDA 215310 for EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, according to § 314.150(d) and waiving its opportunity for a hearing.

For the reasons discussed above, and in accordance with the applicant's request, approval of NDA 215310 for EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, and all amendments and supplements thereto, is withdrawn under § 314.150(d). Distribution of EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, into interstate commerce without an approved application is illegal and subject to regulatory action (see sections 505(a) and 301(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(a) and 331(d)).

Dated: July 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–15371 Filed 7–12–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Advisory Council on Blood Stem Cell Transplantation

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

ACTION: Notice.

SUMMARY: In accordance with the Federal Advisory Committee Act, this notice announces that the Advisory Council on Blood Stem Cell Transplantation (ACBSCT or Advisory Council) has scheduled public meetings. Information about the Advisory Council and the agenda for these meetings can be found on the ACBSCT website at *https://bloodstemcell.hrsa.gov/about/advisory-council.*

DATES: Thursday, August 22, 2024, 2:00 p.m.–6:00 p.m. Eastern Standard Time; and Thursday, October 24, 2024, 2:00 p.m.–6:00 p.m. Eastern Standard Time.

ADDRESSES: Both meetings will be held virtually by webinar. A link to register and join each meeting will be posted at least 10 days prior to the meeting date at: *https://bloodstemcell.hrsa.gov/about/advisory-council.*

FOR FURTHER INFORMATION CONTACT: Shelley Tims Grant, Designated Federal Official, HRSA Health Systems Bureau, Division of Transplantation, 5600 Fishers Lane, 8W–67, Rockville, Maryland 20857; 301–443–8036; or *ACBSCTHRSA@hrsa.gov.*

SUPPLEMENTARY INFORMATION: ACBSCT provides advice and recommendations to the Secretary of Health and Human Services on policy, program development, and other matters of significance concerning the activities under the authority of 42 U.S.C. 274k (Section 379 of the Public Health Service Act), as amended, and Public Law 109–129, as amended. The Advisory Council may transmit its recommendations through the HRSA Administrator on matters related to the activities of the C.W. Bill Young Cell Transplantation Program and National Cord Blood Inventory.

The agenda for the August 22, 2024, meeting is being finalized and may include the following topics: criteria for defining a high-quality cord blood unit for banking specifications; the unmet needs in blood stem cell transplantation and cellular therapy; updates on transplant outcomes by different donor sources; strategies to improve rates of donation for adult blood stem cell donors; and other areas to increase blood stem cell donation and transplantation. The agenda for the October 24, 2024, meeting will be determined based on discussion, priorities, and/or action items from the August 22, 2024, meeting. All agenda items will be posted on the Advisory Council's website no later than 10 days prior to the respective meeting dates. Agenda items are subject to change as priorities dictate. Interested individuals are encouraged to monitor the Advisory Council's website for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Public participants may submit written statements in advance of the scheduled meetings; oral comments will be honored in the order they are requested and may be limited as time allows. Requests to submit a written statement or make oral comments to ACBSCT should be sent to Shelley Tims Grant, using the contact information above, at least 3 business days prior to the meeting.

Individuals who plan to attend and need special assistance or other reasonable accommodations should notify Advisory Council at the address and phone number listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2024–15391 Filed 7–12–24; 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; Rural Communities Opioid Response Program Performance Measures, OMB No 0906–0044, 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 August 14, 2024.

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 Joella Roland, the HRSA Information Collection Clearance Officer, at *paperwork@hrsa.gov* or call (301) 443–3983.

SUPPLEMENTARY INFORMATION: