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NDA 215310 for EXKIVITY (mobocertinib succinate) capsule, EQ 40 mg base, and all amendments and supplements thereto, is withdrawn under § 314.150(d).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: