DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10440]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including the necessity and utility of the proposed information collection for the proper performance of the agency's functions, the accuracy of the estimated burden, ways to enhance the quality, utility, and clarity of the information to be collected, and the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by *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 30-day Review—Open for Public Comments'' or by using the search function.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

FOR FURTHER INFORMATION CONTACT: William Parham at (410) 786–4669.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Collection to Support Eligibility Determinations for Insurance Affordability Programs and Enrollment through Health Benefits Exchanges, Medicaid and CHIP Agencies; *Use:* Section 1413 of the Affordable Care Act directs the Secretary of Health and Human Services to develop and provide to each state a single, streamlined application form that may be used to apply for coverage through a Marketplace and for APTC/CSR, Medicaid, and CHIP (which we refer to collectively as insurance affordability programs). The application must be structured to maximize an applicant's ability to complete the form satisfactorily, taking into account the characteristics of individuals who may qualify for the programs by developing materials at appropriate literacy levels and ensuring accessibility.

Regulations at 45 CFR 155.405(a) provides more detail about the application that must be used by Marketplaces to determine eligibility and to collect information necessary for enrollment. Eligibility standards for the Marketplace are set forth in 45 CFR 155.305. The information will be required of each applicant upon initial application, with some subsequent information collections for the purposes of confirming accuracy of previous submissions and for changes in an applicant's circumstances. 42 CFR 435.907 and § 457.330 establish the standards for state Medicaid and CHIP agencies related to the use of the application. CMS has designed a dynamic electronic application that will tailor the amount of data required from an applicant based on the applicant's circumstances and responses to particular questions in the FFM (please note SBM implementations may vary but the essence of the data collection must adhere to the same parameters). The paper version of the application will not be tailored in the same way but will require only the data necessary to determine eligibility.

Information collected by the Marketplace, Medicaid or CHIP agency will be used to determine eligibility for coverage through the Marketplace and insurance affordability programs (*i.e.,* Medicaid, CHIP, and APTC), and assist consumers in enrolling in a QHP if eligible. Applicants include anyone who may be eligible for coverage through any of these programs. Additionally, this application provides consumers interested in voting resources. *Form Number:* CMS–10440 (OMB control number: 0938–1191); *Frequency:* Annually; *Affected Public:* Private Sector (Business or other for-profits, Not-for-Profit Institutions); *Number of Respondents:* 5,550,000; *Total Annual Responses:* 5,550,000; *Total Annual Hours:* 2,446,440. (For policy questions regarding this collection contact Erin Richardson at 202–619–0630.)

William N. Parham, III,

Director, Division of Information Collections and Regulatory Impacts, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2024–15473 Filed 7–12–24; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–2908]

Cellular and Gene Therapies Interactive Site Tours Program for Regulatory Project Managers and Reviewers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or the Agency) Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP) is announcing the Cellular and Gene Therapies Interactive Site Tours Program (the Interactive Site Tours Program). This program is

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.