Rm. 6200, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, SYMDEKO (tezacaftor/co-packaged with ivacaftor) indicated for the treatment of patients with cystic fibrosis aged 12 years and older who are homozygous for the F508del mutation or who have at least one mutation in the cystic fibrosis transmembrane conductance regulator gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence. Subsequent to this approval, the USPTO received patent term restoration applications for SYMDEKO (U.S. Patent Nos. 7,645,789; 7,776,905; 8,415,387; 8,598,181; 8,623,905; and 9,035,072) from Vertex Pharmaceuticals Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated June 12, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of SYMDEKO represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SYMDEKO is 2,832 days. Of this time, 2,602 days occurred during the testing phase of the regulatory review period, while 230 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* May 15, 2010. The applicant claims May 14, 2010, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was May 15, 2010, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* June 28, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for SYMDEKO (NDA 210491) was initially submitted on June 28, 2017.

3. *The date the application was approved:* February 12, 2018. FDA has verified the applicant's claim that NDA 210491 was approved on February 12, 2018.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 616 days, 864 days, 882 days, 1,001 days, 1,484 days, or 1,532 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: September 18, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21677 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–4085]

Advancing Smoking Cessation: Food and Drug Administration and National Institutes of Health Priorities; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Advancing Smoking Cessation: FDA and NIH Priorities.'' Jointly convened by FDA and the National Institutes of Health (NIH), this public meeting will address the need for novel smoking cessation products to help individuals of all ages, including underserved and vulnerable populations, stop smoking. The overall goal of the meeting is to stimulate novel product development to reduce rates of smoking and related chronic illnesses. The meeting format will include presentations and panel discussions.

DATES: The public meeting will be held in person with an option for virtual attendance on October 21, 2024, from 9 a.m. to 4:30 p.m. Eastern Time. Submit requests to make oral presentations at the public meeting by 5 p.m. Eastern Time, October 1, 2024. Either electronic or written comments on this public meeting must be submitted by November 21, 2024. See the

SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held in the White Oak Great Room at the Food and Drug Administration, White Oak Campus, 10903 New Hampshire Ave., Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://www.fda.gov/about-fda/visitor-information.*

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of November 21, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–2024–N–4085 for ''Advancing Smoking Cessation: FDA and NIH Priorities.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Laura Chilaka, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 877–287–1373, *TobaccoCessation@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to bring together key people in supporting research on and development of new smoking cessation products in order to stimulate novel product development to reduce the burden of smoking and related chronic illnesses. Participants will hear updates on NIH research and FDA operations.

II. Topics for Discussion at the Public Meeting

Session 1. NIH-supported smoking cessation research and areas of opportunity. This session will provide a brief overview of NIH areas of support and identification of gap areas including focus on underserved and vulnerable populations.

Session 2. Update from FDA. This session will provide a brief overview of relevant FDA operations including focus on underserved and vulnerable populations. The session will discuss the regulatory framework for developing smoking cessation drugs, medical devices and their role in smoking cessation, and tobacco pathways.

Session 3. Clinical and community perspectives. This session will offer a concise introduction to smoking cessation treatment considerations from the clinical viewpoint, with a special emphasis on underserved and diverse communities along with potential access and uptake challenges, through the lens of real-world experiences and diversity considerations.

Session 4. Promising targets for development. This session will highlight selected new and emerging areas for intervention development including pharmacologic agents, brain stimulation, and digital therapeutics. In addition, we will discuss the potential endpoints for use in randomized trials of new interventions.

Session 5. Regulatory paths forward. This session will discuss endpoints for smoking cessation drug development programs, evidence necessary to support their role in drug development, clinical outcome assessments, and innovative clinical trial designs and conduct, including trials integrated in clinical practice and clustering in trial design to increase participation from underserved communities.

Session 6. Public comment. Interested persons may present data, information, or views, orally or in writing, on issues

related to cessation and should address the following questions:

1. How can researchers increase enrollment for traditionally underrepresented populations in clinical trials (*e.g.,* racial and ethnic minority populations, LGBTQ+ populations, rural populations)?

2. Would there be interest in an externally led Patient Focused Drug Development (PFDD) meeting to better understand the challenges and barriers to smoking cessation from individuals trying to quit and what additional endpoints can be evaluated in smoking cessation clinical trials?

3. What are some novel targets that could facilitate cigarette cessation product development?

4. What challenges are researchers and/or drug developers facing in their efforts to identify novel targets for smoking cessation therapies?

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website to register: *https://advancingsmokingcessation.eventbrite.com.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone number.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting in person must register by October 15, 2024, 11:59 p.m. Eastern Time. Persons interested in attending this public meeting virtually must register by October 21, 2024, 9 a.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted.

For special accommodations due to a disability, please visit the registration website: *https://advancingsmokingcessation.eventbrite.com.* Please submit special accommodation requests no later than October 7, 2024.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session. We will do our best to accommodate requests to make public comments.

Oral presentations from the public will be scheduled between approximately 3:15 p.m. and 4:15 p.m. Eastern Time on October 21, 2024. Those individuals interested in making formal oral presentations should notify the contact person (see **FOR FURTHER INFORMATION CONTACT**) and submit a brief statement describing the general nature of the evidence or arguments they wish to present and the names and email addresses of proposed participants, on or before October 1, 2024, by 5 p.m. Eastern Time. Topics should address the questions listed in II., Section 6. Individuals making formal oral presentations will not have the capacity to present slides during the public comment session. Individuals may submit presentation materials to the docket on or before November 21, 2024.

Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. Similarly, room for interested persons to participate in person may be limited. If the number of registrants requesting to speak in person during the open public hearing is greater than can be reasonably accommodated in the venue for the in-person portion of the meeting, FDA may conduct a lottery to determine the speakers who will be invited to participate in person. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate in the focused sessions. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin and will select and notify participants as soon as possible to provide speakers with adequate time to prepare. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please visit the following website for more information: *https://advancingsmokingcessation.eventbrite.com.*

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at *https://www.regulations.gov.* It may be viewed at the Dockets Management Staff (see **ADDRESSES**).

(Notice of this meeting is given pursuant to 21 CFR 10.65.)

Dated: September 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–21678 Filed 9–20–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–2396]

Chemistry, Manufacturing, and Controls Development and Readiness Pilot Program; Program Announcement

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing year three of the Chemistry, Manufacturing, and Controls (CMC) Development and Readiness Pilot (CDRP). This program facilitates the expedited CMC development of products under an investigational new drug application (IND) based on the anticipated clinical benefit of earlier patient access to the products. FDA has implemented this pilot program to assist with CMC readiness for products regulated by both the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER) that have accelerated clinical development timelines. To accelerate CMC development and facilitate CMC readiness, the pilot features increased communication between FDA and sponsors and explores the use of science- and risk-based regulatory approaches, as applicable. This notice outlines the eligibility criteria and process for submitting a request to participate in the pilot.

DATES: Starting October 1, 2024, FDA will accept requests to participate in year three of the CDRP program. See the ''Participation'' section of this document for eligibility criteria, instructions on how to submit a request to participate, and selection criteria and process.

FOR FURTHER INFORMATION CONTACT: Tanya Clayton, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 4506, Silver Spring, MD 20993–0002, 301–796–0871; or James Myers, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

For general questions about the CDRP Program for CBER: industry.biologics@fda.hhs.gov.

For general questions about the CDRP Program for CDER: cder-opq-opro-crad-inquiries@fda.hhs.gov.