

FOR FURTHER INFORMATION CONTACT:

Sussan Paydar or Prabhakara Atreya, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, 240-506-4946, CBERVRBPAC@fda.hhs.gov; or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last-minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check FDA's website at <https://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

SUPPLEMENTARY INFORMATION:

Agenda: The meeting presentations will be heard, viewed, captioned, and recorded through an online teleconferencing platform. On March 7, 2023, the committee will meet in open session to discuss and make recommendations on the selection of strains to be included in the influenza virus vaccines for the 2023-2024 influenza season.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its website prior to the meeting, the background material will be made publicly available at the time of the advisory committee meeting, and the background material will be posted on FDA's website after the meeting. Background material is available at <https://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link. The meeting will include slide presentations with audio components to allow the presentation of materials in a manner that most closely resembles an in-person advisory committee meeting.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Dockets (see **ADDRESSES**) on or before February 27, 2023, will be provided to the committee. Comments received after February 27, 2023, and by March 6, 2023, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 1:30 p.m. and 2:30 p.m.

Eastern Time. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, along with their names, email addresses, and direct contact phone numbers of proposed participants, on or before 12 p.m. Eastern Time on February 27, 2023. 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. The contact person will notify interested persons regarding their request to speak by 6 p.m. Eastern Time March 1, 2023.

For press inquiries, please contact the Office of Media Affairs at fdaoma@fda.hhs.gov or 301-796-4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Sussan Paydar or Prabhakara Atreya (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at <https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: February 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-02742 Filed 2-8-23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA-2019-E-1145, FDA-2019-E-1146, and FDA-2019-E-1147]

Determination of Regulatory Review Period for Purposes of Patent Extension; ERLEADA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period

for ERLEADA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 10, 2023. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 8, 2023. See "Petitions" in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: 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 April 10, 2023. 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 Nos. FDA-2019-E-1145, FDA-2019-E-1146, and FDA-2019-E-1147 for "Determination of Regulatory Review Period for Purposes of Patent Extension; ERLEADA." 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, 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 biologic 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, ERLEADA (apalutamide). ERLEADA is indicated for treatment of patients with non-metastatic castration-resistant prostate cancer. Subsequent to this approval, the USPTO received patent term restoration

applications for ERLEADA (U.S. Patent Nos. 8,445,507; 8,802,689; 9,388,159) from The Regents of the University of California, 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 ERLEADA 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 ERLEADA is 2,795 days. Of this time, 2,667 days occurred during the testing phase of the regulatory review period, while 128 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:* June 23, 2010. The applicant claims March 19, 2009, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 23, 2010, which was the first date after receipt of the IND that the investigational studies were allowed to proceed.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* October 10, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for ERLEADA (NDA 210951) was initially submitted on October 10, 2017.

3. *The date the application was approved:* February 14, 2018. FDA has verified the applicant's claim that NDA 210951 was approved on February 14, 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 518 days, 706 days, or 356 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: February 6, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–02743 Filed 2–8–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Meeting of the Advisory Committee on Infant and Maternal Mortality (Formerly the Advisory Committee on Infant Mortality)

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 Committee on Infant and Maternal Mortality (ACIMM or Committee) has scheduled a public meeting. Information about ACIMM and the agenda for this meeting can be found on the ACIMM website at <https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

DATES: March 20, 2023, 11:30 a.m. to 4:30 p.m. Eastern Time and March 21, 2023, 11:30 a.m. to 3:00 p.m. Eastern Time.

ADDRESSES: This meeting will be held by webinar. The webinar link and login information will be available at the ACIMM website before the meeting:

<https://www.hrsa.gov/advisory-committees/infant-mortality/index.html>.

FOR FURTHER INFORMATION CONTACT:

Vanessa Lee, MPH, Designated Federal Official, Maternal and Child Health Bureau, HRSA, 5600 Fishers Lane, Room 18N84, Rockville, Maryland 20857; 301–443–0543; or SACIM@hrsa.gov.

SUPPLEMENTARY INFORMATION:

ACIMM is authorized by section 222 of the Public Health Service Act (42 U.S.C. 217a), as amended. The Committee is governed by provisions of Public Law 92–463, as amended by Public Law 117–286 (5 U.S.C. 10), which sets forth standards for the formation and use of Advisory Committees.

ACIMM advises the Secretary of Health and Human Services (Secretary) on department activities, partnerships, policies, and programs directed at reducing infant mortality, maternal mortality and severe maternal morbidity, and improving the health status of infants and women before, during, and after pregnancy. The Committee provides advice on how to coordinate federal, state, local, tribal, and territorial governmental efforts designed to improve infant mortality, related adverse birth outcomes, maternal health, as well as influence similar efforts in the private and voluntary sectors. The Committee provides guidance and recommendations on the policies, programs, and resources required to address the disparities and inequities in infant mortality, related adverse birth outcomes and maternal health outcomes, including maternal mortality and severe maternal morbidity. With its focus on underlying causes of the disparities and inequities seen in birth outcomes for women and infants, the Committee advises the Secretary on the health, social, economic, and environmental factors contributing to the inequities and proposes structural, policy, and/or systems level changes.

The agenda for the March 20–21, 2023, meeting is being finalized and may include the following topics: an update on the recommendations submitted to the Secretary on improving birth outcomes among American Indian and Alaska Native mothers and infants; a discussion to determine new and continuing priority areas for the Committee; federal updates; and Committee operations. Agenda items are subject to change as priorities dictate. Refer to the ACIMM website listed above for any updated information concerning the meeting.

Members of the public will have the opportunity to provide comments. Requests to submit a written statement or make oral comments to ACIMM should be sent to Vanessa Lee, using the email address above at least 3 business days prior to the meeting. Public participants may submit written statements in advance of the scheduled meeting by emailing SACIM@hrsa.gov. Oral comments will be honored in the order they are requested and may be limited as time allows.

Individuals who plan to attend and need special assistance or a reasonable accommodation should notify Vanessa Lee at the contact information listed above at least 10 business days prior to the meeting.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2023–02791 Filed 2–8–23; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting

AGENCY: Department of Health and Human Services, Office of the Secretary, Office for Civil Rights, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders.

ACTION: Notice of meeting.

SUMMARY: As required by the Federal Advisory Committee Act, the U.S. Department of Health and Human Services (HHS) is hereby giving notice that the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders will hold a meeting on March 14, 2023.

DATES: The Commission will meet on March 14, 2023, from approximately 9:00 a.m. Eastern Time (ET) to approximately 5:30 p.m. ET. The confirmed time and agenda will be posted on the website for the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders: <https://www.hhs.gov/about/whiaanhpi/commission/meetings/index.html> when this information becomes available.

ADDRESSES: The meeting will be live streamed. Registration is required through the following link: <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-registration-517786452217>.

FOR FURTHER INFORMATION CONTACT: Caroline Goon, Designated Federal