

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 October 9, 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:* Extension of a currently

approved collection; *Title of Information Collection:* Hospice Facility Cost Report Form; *Use:* Under the authority of sections 1815(a) and 1833(e) of the Social Security Act (the Act), CMS requires that providers of services participating in the Medicare program submit information to determine costs for health care services rendered to Medicare beneficiaries. CMS requires that providers follow reasonable cost principles under 1861(v)(1)(A) of the Act when completing the Medicare cost report (MCR). The regulations at 42 CFR 413.20 and 413.24 require that providers submit acceptable cost reports on an annual basis and maintain sufficient financial records and statistical data, capable of verification by qualified auditors. In addition, regulations require that providers furnish such Information to the contractor as may be necessary to assure proper payment by the program, receive program payments, and satisfy program overpayment determinations.

CMS regulations at 42 CFR 413.24(f)(4) require that each hospice submit an annual cost report to their contractor in a standard American Standard Code for Information Interchange (ASCII) electronic cost report (ECR) format. A hospice submits the ECR file to contractors using a compact disk (CD), flash drive, or the CMS approved Medicare Cost Report E-filing (MCREF) portal, [URL: <https://mcref.cms.gov>]. The instructions for submission are included in the hospice cost report instructions on page 43-3.

CMS requires the Form CMS-1984-14 to determine a hospice's reasonable costs incurred in furnishing medical services to Medicare beneficiaries. CMS uses the Form CMS-1984-14 for rate setting; payment refinement activities, including developing a market basket; Medicare Trust Fund projections; and program operations support. Additionally, the Medicare Payment Advisory Commission (MedPAC) uses the hospice cost report data to calculate Medicare margins (a measure of the relationship between Medicare's payments and providers' Medicare costs) and analyze data to formulate Medicare Program recommendations to Congress. *Form Number:* CMS-1984-14 (OMB control number: 0938-0758); *Frequency:* Yearly; *Affected Public:* Private Sector, Business or other for-profits, Not for profits institutions; *Number of Respondents:* 6,430; *Total Annual Responses:* 6,430; *Total Annual Hours:* 1,208,840. (For policy questions regarding this collection contact Duncan Gail at 410-786-7278.)

2. *Type of Information Collection:* Extension of a currently approved collection; *Title of Information*

Collection: Organ Procurement Organization Histocompatibility Laboratory Cost Report; *Use:* The Form CMS-216-94 cost report is needed to determine Organ Procurement Organization (OPO)/Histocompatibility Lab (HL) reasonable costs incurred in procuring and transporting organs for transplant into Medicare beneficiaries and reimbursement due to or from the provider. The reasonable costs of procuring and transporting organs cannot be determined for the fiscal year until the OPO/HL files its cost report and costs are verified by the Medicare contractor. During the fiscal year, an interim rate is established based on cost report data from the previous year. The OPO/HL bills the transplant hospital for services rendered. The transplant hospital pays interim payments, approximating reasonable cost, to the OPO/HL. The Form CMS-216-94 cost report is filed by each OPO/HL at the end of its fiscal year and there is a cost report settlement to take into account increases or decreases in costs. The cost report reconciliation and settlement take into consideration the difference between the total reasonable costs minus the total interim payments received or receivable from the transplant centers. *Form Number:* CMS-216-94 (OMB control number: 0938-0102); *Frequency:* Annually; *Affected Public:* Private Sector—Business or other for-profits; *Number of Responses:* 95; *Total Annual Responses:* 95; *Total Annual Hours:* 4,275. (For policy questions regarding this collection contact Luann Piccione at 410-786-5423.)

William N. Parham, III,

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

[FR Doc. 2024-20236 Filed 9-6-24; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2023-E-2484]

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

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 PLUVICTO and is publishing this notice of that determination as required

by law. FDA has made the determination because of the submission of an application 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 November 8, 2024. 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 March 10, 2025. 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 November 8, 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-2023-E-2484 for “Determination of Regulatory Review Period for Purposes of Patent Extension; PLUVICTO.” 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. 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, PLUVICTO (lutetium Lu 177 vipivotide tetraxetan) indicated for the treatment of adult patients with prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer who have been treated with androgen receptor pathway inhibition and taxane-

based chemotherapy. Subsequent to this approval, the USPTO received a patent term restoration application for PLUVICTO (U.S. Patent No. 10,398,791) from Advanced Accelerator Applications USA, Inc. (Agent of Deutsches Krebsforschungszentrum & Ruprecht-Karls-Universität Heidelberg) and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated October 19, 2023, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of PLUVICTO 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 PLUVICTO is 1,881 days. Of this time, 1,643 days occurred during the testing phase of the regulatory review period, while 238 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:* January 29, 2017. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on January 29, 2017.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* July 29, 2021. FDA has verified the applicant's claim that the new drug application (NDA) for PLUVICTO (NDA 215833) was initially submitted on July 29, 2021.

3. *The date the application was approved:* March 23, 2022. FDA has verified the applicant's claim that NDA 215833 was approved on March 23, 2022.

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 application for patent extension, this applicant seeks 523 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 4, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-20246 Filed 9-6-24; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting and Solicitation for Oral and Written Comments Regarding Activities To Support the Advancement of Equity, Justice, and Opportunity for Asian American, Native Hawaiian, and Pacific Islander Communities.

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders.

ACTION: Notice of meeting and solicitation for written and oral comments.

SUMMARY: The U.S. Department of Health and Human Services (HHS) announces the tenth public meeting of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (Commission) and the solicitation of written and oral comment regarding the advancement of equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander (AA and NHPI) communities. The meeting is open to

the public and will be held in Washington, District of Columbia. Virtual attendance will be available through livestream on September 23, 2024. The Commission will also host an in-person, public listening session on September 26, 2024, at the U.S. Department of Transportation Headquarters Building in Washington, District of Columbia. The Commission is working to accomplish its mission to provide independent advice and recommendations to the President on ways to advance equity, justice, and opportunity for AA and NHPI communities.

DATES: The Commission will meet on September 23, 2024, from 9:15 a.m. Eastern Time (ET) to 4 p.m. ET. The final location 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/index.html> when this information becomes available. On September 26, 2024, the Commission will also host an in-person listening session from 11:20 a.m. Eastern Time (ET) to 12:10 p.m. ET during the White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders (WHIAANHPI) Policy Summit in Washington, District of Columbia.

ADDRESSES: Members of the public may attend the meeting on September 23, 2024, virtually. Members of the public may attend the listening session on September 26, 2024, in-person.

Registration is required through the following links:

September 23 meeting (virtual attendance only): <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-tickets-942107116747>

September 26 listening session (in-person attendance only): <https://www.eventbrite.com/e/white-house-aa-nhpi-policy-summit-tickets-942113816787>

FOR FURTHER INFORMATION CONTACT:

Judith Teruya, Lead Designated Federal Officer, President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders, U.S. Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, U.S. Department of Health and Human Services, Hubert Humphrey Building, 620E, 200 Independence Ave. SW, Washington, DC 20201; email: AAANHPICommission@hhs.gov; telephone: (240) 856-3034.

SUPPLEMENTARY INFORMATION: