A. Federal Reserve Bank of St. Louis (Holly A. Rieser, Manager) P.O. Box 442, St. Louis, Missouri 63166–2034. Comments can also be sent electronically to *Comments.applications@stls.frb.org:*

1. *John B. Allee, individually, and as trustee of the John B. Allee Heritage Trust, both of Tipton, Missouri; and Lori A. Woratzeck, as trustee of the Lori A. Woratzeck Heritage Trust, both of California, Missouri;* to become members of the Allee Family Control Group, a group acting in concert, to retain voting shares of Latham Bancshares, Inc., and thereby indirectly retain voting shares of The Tipton Latham Bank, National Association, both of Tipton, Missouri.

Board of Governors of the Federal Reserve System, July 2, 2021.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2021–14577 Filed 7–7–21; 8:45 am]

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GENERAL SERVICES ADMINISTRATION

[Notice-PBS–2021–04; Docket No. 2020–0002; Sequence No. 14]

Revised Notice of Intent/Revised Project Action and Notice of Availability for Land Ports of Entry (LPOE)

AGENCY: Public Buildings Service (PBS), Pacific Rim Division, General Services Administration (GSA).

ACTION: Notice.

SUMMARY: GSA has prepared a Final Environmental Assessment (EA) and separate Finding of No Significant Impact (FONSI) which analyzed the potential impacts from the proposed construction of the Federal Motor Carrier Safety Administration (FMCSA) standalone bus inspection facility at the San Ysidro Land Port of Entry (LPOE) in San Diego, California. The two alternatives analyzed include: New ''Basic'' Facility Buildout; No Build Action. GSA is advising the public that the Final EA and FONSI are available for public comment.

DATES: Due to the COVID–19 pandemic and to ensure the safety of the public, a formal, in-person public meeting will not be held to solicit comments and provide information about the Final EA and FONSI.

ADDRESSES: The Final EA can be viewed on the GSA website at *www.gsa.gov/r9fmcsa.* In addition, copies may be obtained by calling or writing to the individual listed in this notice under the **FOR FURTHER INFORMATION CONTACT** section.

We will consider all comments that we receive on or before Monday, August 9, 2021. You may submit comments by either of the following methods:

- *Electronic Mail: osmahn.kadri@gsa.gov.*
- *Postal Mail/Commercial Delivery:* Send your comment to: Tina Sekula, JMT Inc., 1130 Situs Court, Suite 200, Raleigh, NC 27606.

FOR FURTHER INFORMATION CONTACT:

- *Email:* Osmahn Kadri at *osmahn.kadri@gsa.gov.*
- *Telephone:* (415) 522–3617.
- *NOTE* PLEASE DO NOT MAIL COMMENTS VIA THE U.S. POSTAL SERVICE (USPS) TO THE GSA MAILING ADDRESS AT THIS TIME. USPS MAIL CAN BE SENT TO JMT INC AT THE ADDRESS ABOVE.

SUPPLEMENTARY INFORMATION: The Final EA and FONSI have been prepared to comply with the National Environmental Policy Act (NEPA) of 1969, as amended (42 U.S. Code [U.S.C.] 4321), as implemented by Council on Environmental Quality (CEQ) regulations (40 Code of Federal Regulations [CFR] 1500–1508), and policies of the GSA as the lead federal agency. The EA process provides steps and procedures to evaluate the potential social, economic, and environmental impacts from the construction of the proposed FMCSA Bus Inspection Facility at the San Ysidro LPOE while providing an opportunity for local, state, or federal agencies to provide input and/or comment through scoping, public information meetings, and/or a public hearing. The social, economic, and environmental considerations are evaluated and measured, as defined in the CEQ regulations, by their magnitude of impacts.

The bus inspection station allows for FMCSA to conduct inspections of buses entering the United States from Mexico. FMCSA is required to conduct meaningful vehicle safety inspections and to accommodate vehicles placed out of service because of these inspections. The current bus inspection operations at the San Ysidro LPOE lacks the necessary infrastructure for bus inspections and is not adequate to maintain regular inspections. Therefore, the LPOE does not efficiently address safety needs for the travelling public, FMCSA staff, nor the capacity needs identified in future traffic projections at the LPOE. The lack of dedicated bus inspection infrastructure exposes FMCSA to safety risks while conducting inspections and is not in conformance with current FMCSA safety standards. GSA proposes to construct a new FMCSA Bus Inspection facility on a 1.5-acre parcel located north of the existing LPOE.

A public scoping meeting on the project was held on June 18, 2019. Comments received during the meeting were considered by GSA in a Draft EA. The Draft EA was made available for public comment on May 15, 2020. Comments received during the one-month comment period were considered by GSA in this Final EA. The FONSI, which is based on the Final EA, reflects the GSA's determination that construction of the proposed facility will not have a significant impact on the quality of the human or natural environment.

Russell Larson,

Director, Portfolio Management Division, Pacific Rim Region, Public Buildings Service.

[FR Doc. 2021–14510 Filed 7–7–21; 8:45 am]

BILLING CODE 6820–YF–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2019–E–5322 and FDA–2019–E–5323]

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

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 PIQRAY 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 September 7, 2021. 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 January 4, 2022. 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. Electronic comments must be submitted on or before September 7, 2021. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 7, 2021. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is 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–5322 and FDA–2019–E–5323 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; PIQRAY.'' 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 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, PIQRAY (alpelisib). PIQRAY is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor-positive, human epidermal growth factor receptor 2-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen. Subsequent to this approval, the USPTO received patent term restoration applications for PIQRAY (U.S. Patent Nos. 8,277,462 and 8,476,268) from Novartis AG and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated December 23, 2019, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of PIQRAY 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 PIQRAY is 3,264 days. Of this time, 3,106 days occurred during the testing phase of the regulatory review period, while 158 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 18, 2010. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on June 18, 2010.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 18, 2018. The applicant claims October 26, 2018, as the date the new drug application (NDA) for PIQRAY (NDA 212526) was initially submitted. However, FDA records indicate that NDA 212526 was submitted on December 18, 2018.

3. *The date the application was approved:* May 24, 2019. FDA has verified the applicant's claim that NDA 212526 was approved on May 24, 2019.

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 969 or 1,156 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: June 22, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–14490 Filed 7–7–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Presidential Advisory Council on HIV/AIDS

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice of a virtual meeting.

SUMMARY: As stipulated by the Federal Advisory Committee Act, the U.S. Department of Health and Human Service is hereby giving notice that the Presidential Advisory Council on HIV/AIDS (PACHA or the Council) will be holding the 71st full Council meeting utilizing virtual technology on Tuesday, August 3–Wednesday, August 4, 2021 from 1:00–5:00 p.m. (ET) on both days. The meeting will be open to the public; a public comment session will be held during the meeting. Pre-registration is required to provide public comment during the meeting. To pre-register to attend or to provide public comment, please send an email to *PACHA@hhs.gov* and include your name, organization, and title by close of business Monday, July 26, 2021. If you decide you would like to provide public comment but do not pre-register, you may submit your written statement by emailing *PACHA@hhs.gov* by close of business Wednesday, August 11, 2021. The meeting agenda will be posted on the PACHA page on *HIV.gov* at *https://www.hiv.gov/federal-response/pacha/about-pacha* prior to the meeting.

DATES: The meeting will be held on Tuesday, August 3–Wednesday, August 4, 2021 from 1:00–5:00 p.m. (ET) on both days. This meeting will be conducted utilizing virtual technology.

ADDRESSES: Instructions on attending this meeting virtually will be posted one week prior to the meeting at: *https://www.hiv.gov/federal-response/pacha/about-pacha.*

FOR FURTHER INFORMATION CONTACT: Ms. Caroline Talev, MPA, Public Health Analyst, Presidential Advisory Council on HIV/AIDS, 330 C Street SW, Room L609A, Washington, DC 20024; (202) 795–7622 or *PACHA@hhs.gov.* Additional information can be obtained by accessing the Council's page on the *HIV.gov* site at *www.hiv.gov/pacha.*

SUPPLEMENTARY INFORMATION: PACHA was established by Executive Order 12963, dated June 14, 1995, as amended by Executive Order 13009, dated June 14, 1996 and is currently operating under the authority given in Executive Order 13889, dated September 27, 2019. The Council was established to provide advice, information, and recommendations to the Secretary regarding programs and policies intended to promote effective prevention and care of HIV infection and AIDS. The functions of the Council are solely advisory in nature.

The Council consists of not more than 25 members. Council members are selected from prominent community leaders with particular expertise in, or knowledge of, matters concerning HIV and AIDS, public health, global health, philanthropy, marketing or business, as well as other national leaders held in high esteem from other sectors of society. Council members are appointed by the Secretary or designee, in consultation with the White House.

Dated: June 9, 2021.

Caroline Talev,

Management Analyst, Office of Infectious Disease and HIV/AIDS Policy, Alternate Designated Federal Officer, Presidential Advisory Council on HIV/AIDS, Office of the Assistant Secretary for Health, Department of Health and Human Services.

[FR Doc. 2021–14496 Filed 7–7–21; 8:45 am]

BILLING CODE 4150–43–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which