

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](https://www.hiv.gov/federal-response/pacha/about-pacha) 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](https://www.hiv.gov/pacha) 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