

## 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](mailto: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](mailto:PACHA@hhs.gov) by close of business Wednesday, August 11, 2021. The meeting agenda will be posted on the PACHA page on [HIV.gov](http://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](mailto:PACHA@hhs.gov).

Additional information can be obtained by accessing the Council's page on the [HIV.gov](http://HIV.gov) site at [www.hiv.gov/pacha](http://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

would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* Center for Scientific Review Special Emphasis Panel; RFA Panel: HEALthy Brain and Child Development Study Consortium Administrative Cores (U24).

*Date:* July 7, 2021.

*Time:* 10:00 a.m. to 4:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

*Contact Person:* Gianina Ramona Dumitrescu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4193-C, Bethesda, MD 28092, (301) 827-0696, [dumitrescurg@csr.nih.gov](mailto:dumitrescurg@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: July 1, 2021.

**Melanie J. Pantoja,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2021-14531 Filed 7-7-21; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2021-0233]

#### Request for Information on Coast Guard Programs, Regulations, and Policies for Addressing Climate Change

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for information.

**SUMMARY:** The U.S. Coast Guard seeks input from the public on specific Coast Guard programs, regulations, policies, and procedures that the Coast Guard should consider changing to combat and respond to climate change. This information will help the Coast Guard effectively achieve its missions in a manner that advances the Administration's urgent priorities of climate change mitigation, adaptation, and resilience. We further seek this input to ensure that we are implementing programs, policies, and activities that address (1) the cumulative effects of environmental damage, above all from climate change and (2) the disproportionately high, adverse

climate-related impacts on disadvantaged communities, while also promoting a safe, secure, and resilient marine transportation system that facilitates commerce and secures national security interests.

**DATES:** Comments must be submitted to the online docket via <https://www.regulations.gov> on or before October 6, 2021.

**ADDRESSES:** You may submit comments identified by docket number USCG-2021-0233 using the Federal eRulemaking Portal at <https://www.regulations.gov>. See the "Public Participation and Request for Comments" portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

**FOR FURTHER INFORMATION CONTACT:** For information about this document call or email Mr. Tim Brown, Coast Guard; telephone 202-372-2358, email [Timothy.M.Brown@uscg.mil](mailto:Timothy.M.Brown@uscg.mil).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Public Participation and Comments**

We encourage you to submit comments (or related material) responding to this request for information. We will consider all submissions and may adjust agency policy based on your input. If you submit a comment, please include the docket number for this notice, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

*Methods for submitting comments.* We encourage you to submit comments through the Federal eRulemaking Portal at <https://www.regulations.gov>. To do so, go to <https://www.regulations.gov>, type USCG-2021-0233 in the search box and click "Search." Next, look for this document in the Search Results column, and click on it. Then click on the Comment option. If your material cannot be submitted using <https://www.regulations.gov>, contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Public comments will be in our online docket at <https://www.regulations.gov> and can be viewed by following that website's instructions provided on its Frequently Asked Questions page. We review all material received, but we may choose not to post off-topic, inappropriate, or duplicate comments that we receive.

*Personal information.* We accept anonymous submissions. Comments we post to <https://www.regulations.gov> will include any personal information you have provided. For more about privacy

and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

## **II. Background**

The Coast Guard is issuing this request for information in response to Executive Orders 13990 and 14008, which have established the protection of public health and the environment, the mitigation of climate change, and the advancement of environmental justice as policy priorities for this Administration. Executive Order 13990, *Protecting Public Health and the Environment and Restoring Science To Tackle the Climate Crisis*,<sup>1</sup> states that the Administration's policy is to listen to science; to ensure access to clean air and water; to limit exposure to dangerous chemicals and pesticides; to hold polluters accountable, including those that disproportionately harm communities of color and low-income communities; to reduce greenhouse gas emissions; to bolster resilience to the impacts of climate change; to restore and expand our national treasures and monuments; and to prioritize both environmental justice and the creation of the well-paying union jobs necessary to deliver on these goals. The Order directs agencies to seek input from the public and stakeholders, including State, local, Tribal, and territorial officials, scientists, labor unions, environmental advocates, and environmental justice organizations.

The Order directs agencies immediately to review all regulations, orders, guidance documents, policies, or any other similar agency actions undertaken between January 20, 2017, and January 20, 2021, that are inconsistent with the listed policy priorities. In addition, agencies are directed to contemplate and consider whether to take any additional agency actions, within their authority, to fully enforce the listed policy priorities.

Executive Order 14008, *Tackling the Climate Crisis at Home and Abroad*,<sup>2</sup> further places the climate crisis at the center of U.S. foreign policy and national security by deploying the full capacity of its agencies to combat the climate crisis, by implementing a Government-wide approach that reduces climate pollution in every sector of the economy; by increasing resilience to the impacts of climate change; by protecting public health; by conserving our lands, waters, and biodiversity; by delivering environmental justice; and by spurring

<sup>1</sup> 86 FR 7037 (published Jan. 25, 2021).

<sup>2</sup> 86 FR 7619 (published Feb. 1, 2021).