

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]

BILLING CODE 4164–01–P

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 log-in 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-nhpis-registration-517786452217>.

FOR FURTHER INFORMATION CONTACT: Caroline Goon, 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 for Civil Rights, Hubert H. Humphrey Building, Room 515F, 200 Independence Ave SW, Washington, DC 20201; email: AANHPICommission@hhs.gov; telephone: (202) 619-0403, fax: (202) 619-3818.

SUPPLEMENTARY INFORMATION: The meeting is the fifth in a series of Federal advisory committee meetings regarding the development of recommendations to promote 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 live streamed. The Commission, co-chaired by HHS Secretary Xavier Becerra and the U.S. Trade Representative Ambassador Katherine Tai, advises the President on: the development, monitoring, and coordination of executive branch efforts to advance equity, justice, and opportunity for AA and NHPI communities in the United States, including efforts to close gaps in health, socioeconomic, employment, and educational outcomes; policies to address and end anti-Asian bias, xenophobia, racism, and nativism, and opportunities for the executive branch to advance inclusion, belonging, and public awareness of the diversity and accomplishments of AA and NHPI people, cultures, and histories; policies, programs, and initiatives to prevent, report, respond to, and track anti-Asian hate crimes and hate incidents; ways in which the Federal Government can build on the capacity and contributions of AA and NHPI communities through equitable Federal funding, grantmaking, and employment opportunities; policies and practices to improve research and equitable data disaggregation regarding AA and NHPI communities; policies and practices to improve language access services to ensure AA and NHPI communities can access Federal programs and services; and strategies to increase public-and private-sector collaboration, and community involvement in improving the safety and socioeconomic, health, educational, occupational, and environmental well-being of AA and NHPI communities.

More information is available on the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders website at <https://www.hhs.gov/about/whiaanhpi/commission/index.html>. Information on the 25 members of the President's Advisory Commission on Asian

Americans, Native Hawaiians, and Pacific Islanders is available at <https://www.hhs.gov/about/whiaanhpi/commission/commissioners/index.html>.

Purpose of Meeting: The President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders, authorized by Executive Order 14031, will meet to discuss full and draft recommendations by the Commission's six Subcommittees on ways to advance equity, justice, and opportunity for Asian American, Native Hawaiian, and Pacific Islander communities. The Subcommittees are: Belonging, Inclusion, Anti-Asian Hate, Anti-Discrimination; Data Disaggregation; Language Access; Economic Equity; Health Equity; and Immigration and Citizenship Status.

Background: Asian American, Native Hawaiian, and Pacific Islander communities are among the fastest growing racial and ethnic populations in the United States according to the U.S. Census Bureau. However, in recent years, AA and NHPI individuals have faced increasing hate crimes and incidents that threaten their safety, as well as harmful stereotypes that often ignore socioeconomic, health, and educational disparities impacting these diverse communities. Anti-Asian violence increased during the COVID-19 pandemic, casting a shadow of fear and anxiety over many AA and NHPI communities. However, even before the pandemic, AA and NHPI communities in the United States have faced xenophobia, religious discrimination, racism, and violence. At the same time, AA and NHPI communities are overrepresented in the pandemic's essential workforce in healthcare, food supply, education, and childcare, with more than four million AA and NHPIs manning the frontlines throughout the pandemic.

Many AA and NHPI communities were also disproportionately burdened by the COVID-19 public health crisis. In addition to the disproportionate health impacts of COVID-19, particularly on Native Hawaiian and Pacific Islander communities, many AA and NHPI workers, families, and small businesses also faced devastating economic losses that must be addressed.

The challenges AA and NHPI communities face are often exacerbated by a lack of adequate data disaggregation and language access. The President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders works to advise the President on executive branch efforts to address these challenges and advance equity, justice, and opportunity for AA and NHPI communities.

Public Participation at Meeting: Members of the public are invited to view the Commission meeting. Registration is required through the following link: <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpis-registration-517786452217>. Please note that there will be no opportunity for oral public comments during the meeting of the Commission. However, written comments are welcomed throughout the development of the Commission's recommendations to promote equity, justice, and opportunity for Asian Americans, Native Hawaiians, and Pacific Islanders and may be emailed to AANHPICommission@hhs.gov.

Authority: Executive Order 14031. The President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (Commission) is governed by provisions of the Federal Advisory Committee Act (FACA), Public Law 92-463, as amended (5 U.S.C. App.), which sets forth standards for the formation and use of Federal advisory committees.

Krystal Ka'ai,

Executive Director, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders, President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders.

[FR Doc. 2023-02719 Filed 2-8-23; 8:45 am]

BILLING CODE 4153-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Closed Meetings

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

The meetings 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: National Cancer Institute Special Emphasis Panel; Cancer Target Discovery and Development Network, CTD2 (U01).

Date: March 7, 2023.