

fabricated; and inducing sponsors and contract research organizations to pay money for Ms. Villaman-Bencosme and her co-conspirators' own benefit. On or about October 25, 2013, Ms. Villaman-Bencosme entered into a contract with a Contract Research Organization retained by a drug manufacturer (Sponsor) to serve as a clinical investigator for a clinical trial initiated by the Sponsor. The study was for an investigational drug intended to treat pediatric asthma in children between the ages of 4 and 11 years. As the clinical investigator Ms. Villaman-Bencosme was responsible for all aspects of the study to include ensuring that subjects provided informed consent and understood the risks of participating in the study, reporting adverse events to the Sponsor, and maintaining honest and accurate records known as "case histories." Instead, Ms. Villaman-Bencosme used personal identification information from pediatric patient medical records maintained at her private medical practice to falsify case histories. This included a number of false details. Ms. Villaman-Bencosme made it appear that: The study subjects satisfied the eligibility criteria to participate in the study; the subjects received a physical examination from her; the patients received the study drug at the study site; the patients returned the study drug to the study site; and the patients received payment for visits to the study site.

As a result of this conviction, FDA sent Ms. Villaman-Bencosme by certified mail on November 3, 2021, a notice proposing to permanently debar her from providing services in any capacity to a person that has an approved or pending drug product application. The proposal was based on a finding, under section 306(a)(2)(A) of the FD&C Act, that Ms. Villaman-Bencosme was convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act. The proposal also offered Ms. Villaman-Bencosme an opportunity to request a hearing, providing her 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted an election not to use the opportunity for a hearing and a waiver of any contentions concerning this action. Ms. Villaman-Bencosme received the proposal on November 13, 2021. She did not request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and any

contentions concerning her debarment (21 CFR part 12).

## II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(a)(2)(A) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Villaman-Bencosme has been convicted of a felony under Federal law for conduct relating to the development or approval, including the process of development or approval, of any drug product under the FD&C Act.

As a result of the foregoing finding, Ms. Villaman-Bencosme, is permanently debarred from providing services in any capacity to a person with an approved or pending drug product application, effective (see **DATES**) (see sections 306(a)(2)(A) and 306(c)(2)(A)(ii) of the FD&C Act). Any person with an approved or pending drug product application who knowingly employs or retains as a consultant or contractor, or otherwise uses the services of Ms. Villaman-Bencosme, in any capacity during her debarment, will be subject to civil money penalties (section 307(a)(6) of the FD&C Act (21 U.S.C. 335b(a)(6))). If Ms. Villaman-Bencosme provides services in any capacity to a person with an approved or pending drug product application during her period of debarment, she will be subject to civil money penalties (section 307(a)(7) of the FD&C Act). In addition, FDA will not accept or review any abbreviated new drug application from Ms. Villaman-Bencosme during her period of debarment, other than in connection with an audit under section 306 of the FD&C Act (section 306(c)(1)(B) of the FD&C Act). Note that, for purposes of sections 306 and 307 of the FD&C Act, a "drug product" is defined as a "drug subject to regulation under section 505, 512, or 802 of this Act [(21 U.S.C. 355, 360b, 382)] or under section 351 of the Public Health Service Act [(42 U.S.C. 262)]" (section 201(dd) of the FD&C Act (21 U.S.C. 321(dd))).

Any application by Ms. Villaman-Bencosme for special termination of debarment under section 306(d)(4) of the FD&C Act should be identified with Docket No. FDA-2021-N-0317 and sent to the Dockets Management Staff (see **ADDRESSES**). The public availability of information in these submissions is governed by 21 CFR 10.20.

Publicly available submissions will be placed in the docket and will be viewable at <https://www.regulations.gov> or at the Dockets Management Staff (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

Dated: April 12, 2022.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## 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 May 12, 2022. The meeting is the second 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. Registration is required through the following link: <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-registration-311578077417>. The Commission, co-chaired by HHS Secretary Xavier Becerra and the U.S. Trade Representative Ambassador Katherine Tai, will advise the President on: (i) 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; (ii) 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; (iii) policies, programs, and initiatives to prevent, report, respond to, and track anti-Asian hate crimes and hate incidents; (iv) 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; (v) policies and practices to improve research and equitable data disaggregation regarding AA and NHPI communities; (vi) policies and practices to improve language access services to ensure AA and NHPI communities can access Federal programs and services; and (vii) 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.

**DATES:** The Commission will meet on May 12, 2022 from 12:30 p.m. to approximately 5:30 p.m. Eastern Time (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/index.html> when this information becomes available.

**LOCATION:** 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-nhpi-registration-311578077417>.

**FOR FURTHER INFORMATION CONTACT:** Larissa Bungo, 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: [whiaanhpi@hhs.gov](mailto:whiaanhpi@hhs.gov); telephone: (202) 619-0403, fax: (202) 619-3818.

**SUPPLEMENTARY INFORMATION:** 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>. The names of the 25 members of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders are 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 individuals and communities have molded the American experience, and the contributions and achievements of AA and NHPI communities make the United States stronger and more vibrant. The richness of America's multicultural democracy is strengthened by the diversity of AA and NHPI communities and the many cultures and languages of AA and NHPI individuals in the United States, who collectively constitute the fastest growing racial group in the Nation and make rich contributions to our society, our economy, and our culture.

Systemic barriers to equity, justice, and opportunity put the American dream out of reach of many AA and NHPI communities. Many AA and NHPI individuals face persistent disparities in socioeconomic, health, and educational outcomes. Linguistic isolation and lack of access to language-assistance services continue to lock many AA and NHPI individuals out of opportunities. Data collection practices fail to measure and reflect the diversity of AA and NHPI populations. Failure to disaggregate data contributes to enduring stereotypes about Asian Americans as a "model minority" and obscures disparities within AA and NHPI communities.

Tragic acts of anti-Asian violence have increased during the COVID-19 pandemic, casting a shadow of fear and grief over many AA and NHPI communities, in particular East Asian communities. Long before this pandemic, AA and NHPI communities in the United States, including South Asian and Southeast Asian communities, have faced persistent 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. Additionally, while they make up just four percent of registered nurses in the U.S., Filipino nurses accounted for 32 percent of nurse lives lost to COVID-19 in 2020.

Many AA and NHPI communities, and in particular Native Hawaiian and Pacific Islander communities, have also been disproportionately burdened by the COVID-19 public health crisis.

Evidence suggests that Native Hawaiians and Pacific Islanders are three times more likely to contract COVID-19 compared to white people and nearly twice as likely to die from the disease. On top of these health inequities, many AA and NHPI workers, families, and small businesses have faced devastating economic losses during this crisis, which must be addressed.

**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-nhpi-registration-311578077417>. 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](mailto: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 and President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more