

Application No.	Drug	Applicant
ANDA 090177 .....	Oxycodone and Acetaminophen Tablets, 3.25 milligrams (mg); 2.5 mg, 325 mg; 5 mg, 325 mg; 7.5 mg, 325 mg; 10 mg, 500 mg; 7.5 mg, 650 mg; 10 mg.	Dr. Reddy's Laboratories, Inc., U.S. Agent for Dr. Reddy's Laboratories SA, 107 College Rd. East, Princeton NJ 08540.
ANDA 091313 .....	Oxycodone Hydrochloride (HCl) Tablets, 5 mg, 10 mg, 15 mg, 20 mg, 30 mg.	Do.
ANDA 091670 .....	Oxycodone and Aspirin Tablets, 325 mg; 4.8355 mg .....	Do.
ANDA 203107 .....	Oxycodone HCl Capsules, 5 mg .....	Do.
ANDA 203335 .....	Butalbital, Aspirin, Caffeine, and Codeine Phosphate Capsules, 325 mg; 50 mg; 40 mg; 30 mg.	Do.
ANDA 203807 .....	Clozapine Tablets, 25 mg, 50 mg, 100 mg, 200 mg .....	Do.
ANDA 204092 .....	Oxycodone HCl Oral Solution 100 mg/5 milliliters .....	Do.
ANDA 205386 .....	Morphine Sulfate Extended-Release Tablets, 15 mg, 30 mg, 60 mg, 100 mg.	Do.
ANDA 206329 .....	Fentanyl Citrate Tablets, Equivalent to (EQ) 0.1 mg base, EQ 0.2 mg base, EQ 0.3 mg base, EQ 0.4 mg base, EQ 0.6 mg base, EQ 0.8 mg base.	Do.
ANDA 206953 .....	Buprenorphine HCl and Naloxone HCl Tablets, EQ 2 mg base, EQ 0.5 mg base; EQ 8 mg base, EQ 2 mg base.	Do.
ANDA 207270 .....	Morphine Sulfate Tablets, 15 mg, 30 mg .....	Do.

Therefore, approval of the applications listed in the table, and all amendments and supplements thereto, is hereby withdrawn as of November 3, 2023. Approval of each entire application is withdrawn, including any strengths and dosage forms inadvertently missing from the table. Introduction or delivery for introduction into interstate commerce of products without approved new drug applications violates section 301(a) and (d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331(a) and (d)). Drug products that are listed in the table that are in inventory on November 3, 2023 may continue to be dispensed until the inventories have been depleted or the drug products have reached their expiration dates or otherwise become violative, whichever occurs first.

Dated: September 29, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023-21992 Filed 10-3-23; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Announcement of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Meeting and Solicitation for Written Comments

**AGENCY:** Department of Health and Human Services, Office of the Secretary, Office of Intergovernmental and External Affairs, White House Initiative on Asian Americans, Native Hawaiians, and Pacific Islanders.

**ACTION:** Notice of meeting and solicitation for written comments.

**SUMMARY:** The U.S. Department of Health and Human Services (HHS) announces the next meeting of the President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders (Commission) and the solicitation of written comments regarding the advancement of 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 held in Washington, DC on October 25 and October 26, 2023. Virtual attendance will be available through livestream. The Commission is working to accomplish its mission to provide independent advice and recommendations to the President on ways to advance equity, justice, and opportunity for AA and NHPI communities.

**DATES:** The Commission will meet on October 25, 2023, from 9:00 a.m. Eastern Time (ET) to 4:30 p.m. ET and October 26, 2023, from 9:00 a.m. ET to 2:00 p.m. ET. The final location 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.

**ADDRESSES:** Members of the public may attend virtually. Registration is required through the following link: <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-tickets-715434733547?aff=oddttdcreator>.

**FOR FURTHER INFORMATION CONTACT:** Viviane Chao, 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 of Intergovernmental and External Affairs, Hubert H. Humphrey Building, Room 620E, 200 Independence Ave. SW, Washington, DC 20201; email: [AANHPICommission@hhs.gov](mailto:AANHPICommission@hhs.gov); telephone: (202) 690-6060.

**SUPPLEMENTARY INFORMATION:** The meeting is the seventh in a series of Federal advisory committee meetings regarding the development of recommendations to advance equity, justice, and opportunity for 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.

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 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.

During the COVID-19 pandemic, tragic acts of anti-Asian violence increased and cast a shadow of fear and grief over many AA and NHPI communities. However, even before the pandemic, AA and NHPI communities in the United States have faced persistent xenophobia, religious discrimination, racism, and violence.

At the same time, AA and NHPI communities were 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. Many AA and NHPI workers, families, and small businesses also faced devastating economic losses during this time.

Additionally, health and economic inequities faced by Native Hawaiian and Pacific Islander communities worsened during the COVID-19 pandemic, with evidence suggesting they were twice as likely to die from the disease compared to white counterparts.

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 may attend virtually. Registration is required through the following link: <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-tickets-715434733547?aff=oddtcreator>.

**Written public comments:** 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 [AAANHPICommission@hhs.gov](mailto:AAANHPICommission@hhs.gov) at any time. Respond concisely and in plain language. You may use any structure or layout that presents your information well. You may include links to online material or interactive presentations. Clearly mark any proprietary information and place it in its own section or file. Your response will become Government property, and we may publish some of its non-proprietary content.

**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.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Indian Health Service

#### Special Diabetes Program for Indians

*Announcement Type:* New.

*Funding Announcement Number:*

HHS-2024-IHS-SDPI-0001.

*Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number:* 93.237.

#### Key Dates

*Application Deadline Date:* November 29, 2023.

*Earliest Anticipated Start Date:* January 1, 2024.

#### I. Funding Opportunity Description

##### Statutory Authority

The Indian Health Service (IHS) is accepting applications for the Special Diabetes Program for Indians (SDPI—formerly Community-Directed SDPI). This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C. 2001(a); and Section 330C of the Public Health Service Act, codified at 42 U.S.C. 254c-3. The Assistance Listings section of SAM.gov (<https://sam.gov/content/home>) describes this program under 93.237.

##### Background

Diabetes is a complex and costly chronic disease that requires tremendous long-term efforts to prevent and treat. Although diabetes is a nationwide public health problem, American Indian/Alaska Native (AI/AN) people are disproportionately affected. In 2019, 14.5 percent of AI/AN people aged 18 years or older had diagnosed diabetes, compared to 7.4 percent of non-Hispanic white people [CDC, 2021. <https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-diabetes.html>]. In addition, AI/AN people have higher rates of diabetes-related morbidity and mortality than the general U.S. population [O'Connell, 2010 (<https://diabetesjournals.org/care/article/33/7/1463/39326/Racial-Disparities-in-Health-Status-A-comparison-of>); Cho, 2014 (<http://ajph.aphapublications.org/doi/full/10.2105/AJPH.2014.301968>)]. Strategies to address the prevention and treatment of diabetes in AI/AN communities are urgently needed.

In response to the burgeoning diabetes epidemic among AI/AN people, Congress established the SDPI through the Balanced Budget Act of 1997. SDPI is a \$150 million per year program that provides awards for diabetes treatment and prevention services. The IHS