

SUPPLEMENTARY INFORMATION:**I. Background**

FDA is announcing the availability of a draft guidance for industry #279 entitled “Demonstrating Bioequivalence for Type A Medicated Articles Containing Active Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.” Section 512(c)(2)(A)(vi) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360b(c)(2)(A)(vi)) requires that generic new animal drug products be shown to be bioequivalent to the reference listed new animal drug (RLNAD), and section 512(n)(1)(E) of the FD&C Act requires that the sponsor provide information to show that the proposed product is bioequivalent to the RLNAD.

FDA’s Center for Veterinary Medicine (CVM) has issued guidance on demonstrating bioequivalence through *in vivo* studies, and guidance on product types that may be eligible for a waiver from the requirement to perform *in vivo* bioequivalence studies, including oral solutions and other solubilized forms, parenteral solutions, some topically applied dosage forms (see Guidance for Industry #35, “Bioequivalence Guidance”) and TAMAs with APIs that are considered to be water soluble (see Guidance for Industry #171, “Demonstrating Bioequivalence for Soluble Powder Oral Dosage Form Products, and Type A Medicated Articles Manufactured from Active Pharmaceutical Ingredients Considered To Be Soluble in Aqueous Media”). However, these guidance documents do not specifically address the unique challenges associated with demonstrating bioequivalence of TAMAs containing poorly soluble, locally acting APIs. Therefore, this guidance is intended to address these unique challenges. In particular, when the TAMA is not a candidate for a waiver from the requirement to conduct *in vivo* blood level bioequivalence studies, CVM recommends via this guidance that product bioequivalence be demonstrated using alternative test approaches to those relying exclusively on animal testing. This draft guidance, when finalized, is intended to address these situations.

This level 1 draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on “Demonstrating Bioequivalence for Type A Medicated Articles Containing Active

Pharmaceutical Ingredient(s) Considered To Be Poorly Soluble in Aqueous Media, That Exhibit Little to No Systemic Bioavailability, and Are Locally Acting.” It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in section 512(n)(1) of the FD&C Act have been approved under OMB control number 0910–0669.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/animal-veterinary/guidance-regulations/guidance-industry>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: May 31, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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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 and Oral 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 and oral 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 and oral comment 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 Honolulu, Hawaii. Virtual attendance will be available through livestream for July 6; in-person attendance is available for July 7, 2023. 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 July 6, 2023, from 2:30 p.m. Eastern Time (ET) to 11:30 p.m. ET and July 7, 2023, from 3:00 p.m. ET to 6:00 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 or in person, depending on the portion of the meeting. Registration is required through the following links:

July 6 (virtual attendance only): <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-tickets-646261494527>

July 7 (in-person attendance only): <https://www.eventbrite.com/e/white-house-initiative-aa-and-nhpi-economic-summer-honolulu-tickets-649191698847>

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; telephone: (202) 951–0235.

SUPPLEMENTARY INFORMATION: The meeting is the sixth 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.

Tragic acts of anti-Asian violence 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 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 throughout the pandemic.

Many AA and NHPI communities, and in particular Native Hawaiian and Pacific Islander communities, were disproportionately burdened by the COVID-19 public health crisis. Evidence suggests that Native Hawaiians and Pacific Islanders were 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 faced devastating economic losses during the crisis.

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 or in person, depending on the portion of the meeting. Registration is required through the following links:

July 6 (virtual attendance only): <https://www.eventbrite.com/e/meeting-of-the-presidents-advisory-commission-on-aa-and-nhpi-tickets-646261494527>

July 7 (in-person attendance only): <https://www.eventbrite.com/e/white-house-initiative-aa-and-nhpi-economic-summit-honolulu-tickets-649191698847>

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 AANHPICommission@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 respond to some or all of our questions, and you can suggest other factors or relevant questions. You may also 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.

Oral public comments: Individuals may submit a request to make an oral public comment at the July 7, 2023, meeting in response to the questions below. Advance copy of public comment must be sent via email at AANHPICommission@hhs.gov with the subject line "PACAANHPI: In-person Response to <insert the issue and question>" no later than 11:59 p.m. ET on Friday, June 23, 2023. Submissions received after the deadline will not be considered for oral public comment.

Registration for oral public comment is on a first-come, first-served basis. Comments are limited to two (2) minutes or less. After the maximum number of speakers is exceeded, individuals registered to provide oral comment will be placed on a wait list and notified should an opening become available. You will be notified via email no later than July 5, 2023, if you have been identified to provide in-person public comment.

The Commission is particularly interested in soliciting comments on the following questions:

1. Belonging, Inclusion, Anti-Asian Hate, Anti-Discrimination Subcommittee Questions:

a. Please provide feedback on the experiences of Asian Americans, Native Hawaiians, and Pacific Islanders in the Child Protection/Child Welfare system.

b. What are promising practices, services, or prevention and intervention strategies that advance the well-being of AA and NHPI children and families who encounter the child protection/child welfare systems?

2. Language Access Subcommittee Questions:

a. How can the Federal Government promote the preservation, teaching, learning of, maintenance and utilization of AA and NHPI languages?

b. Are there any programs you recommend the Commission examine that provide meaningful language access to government benefits and services to persons with limited English proficiency?

3. Economic Equity Subcommittee Questions:

a. To what extent does the Native Hawaiian community have access to or understand how to access resources for job training and housing assistance at the local, state, and federal level?

b. How familiar is the public with the federal government resources available to support small businesses, loans, or grants?

c. How can the government better provide culturally sensitive and affordable housing for AA and NHPI communities?

4. Health Equity Subcommittee Questions:

a. What are the mental health concerns impacting communities in the Pacific Islands and what are some of the ways communities are trying to address them?

b. What are the biggest concerns around health for Native Hawaiians?

c. What are some of the biggest barriers to obtaining health care in Hawaii and other Pacific Islands?

d. What could improve your communities' ability to obtain federal services such as housing assistance, SSI/SSDI, SNAP/WIC, FEMA assistance, etc.?

5. Immigration and Citizenship Status Subcommittee Questions:

a. What are the main policy implications for Pacific Islanders who have either immigrated or moved away from their island homelands to other locations in the United States?

b. Pacific Islanders have a unique history with the United States that differs from most immigrants or migrants to this country. What should the responsibility of the federal government be to Pacific Islanders in light of this historical relationship?

c. As immigration-related agencies within the U.S. Department of Homeland Security (DHS) like the U.S. Citizenship and Immigration Services (USCIS), Immigration and Customs Enforcement (ICE), and Customs and Border Protection (CBP), work to expand language services, how should they decide which languages and which processes should be prioritized for implementation? Are there specific forms or processes that DHS agencies should prioritize providing language services for immediately? If so, which forms and language translations should be prioritized?

d. What can be done to address negative stereotypes and improve group relations between Pacific Islanders and other communities both in the Pacific Islands and throughout the United States?

Authority: Executive Order 14031. The President's Advisory Commission on Asian Americans, Native Hawaiians, and Pacific Islanders is governed by provisions of the Federal Advisory Committee Act, 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

National Institutes of Health

National Toxicology Program Board of Scientific Counselors; Announcement of Meeting; Request for Comments

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This notice announces the next meeting of the National Toxicology Program (NTP) Board of Scientific Counselors (BSC). The BSC, a federally chartered, external advisory group composed of scientists from the public and private sectors, will review and provide advice on programmatic activities. This meeting is a virtual meeting and is open to the public. Written comments will be accepted, and registration is required to present oral comments.

DATES:

Meeting: Scheduled for July 11, 2023, 11:00 a.m.–1:15 p.m. Eastern Daylight Time (EDT). Ending times are approximate; meeting may end earlier or run later.

Written Public Comment

Submissions: Deadline is July 5, 2023; 5:00 p.m. EDT.

Registration for Oral Comments: Deadline is July 5, 2023; 5:00 p.m. EDT.

ADDRESSES:

Meeting Web Page: The preliminary agenda, registration, and other meeting materials will be available at <https://ntp.niehs.nih.gov/go/165> by June 12, 2023.

Virtual Meeting: A link to the URL for viewing the virtual meeting will be provided on the meeting web page by noon the day before the meeting.

FOR FURTHER INFORMATION CONTACT: Dr. Milene Brownlow, Designated Federal Officer for the BSC, Office of Policy, Review, and Outreach, Division of Translational Toxicology, NIEHS. Phone: 984-287-3364, Email: milene.brownlow@nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2136, Durham, NC 27713.

SUPPLEMENTARY INFORMATION: The BSC will provide input to the NTP on programmatic activities and issues. The preliminary agenda topics include a presentation on needed research capabilities to support predictive toxicology and evidence evaluation, including the development and implementation of computational, alternative, literature-based, and quality assessment tools and methodologies. The NIEHS proposes to obtain support for these activities via contract mechanism due to the scope of the required capabilities and availability of personnel with relevant experience to perform these activities exceeding the internal resources available. The preliminary agenda, roster of BSC members, background materials, public comments, and any additional information, when available, will be posted on the BSC meeting web page (<https://ntp.niehs.nih.gov/go/165>) or may be requested in hardcopy from the Designated Federal Officer for the BSC. Following the meeting, summary minutes will be prepared and made available on the BSC meeting web page within 90 calendar days of the meeting.

Meeting Attendance Registration: The meeting is open to the public with time scheduled for oral public comments. Registration is not required to view the virtual meeting; the URL for the virtual meeting will be provided on the BSC meeting web page (<https://ntp.niehs.nih.gov/go/165>) by noon the day before the meeting. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Written Public Comments: NTP invites written public comments. Guidelines for public comments are available at https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.

The deadline for submission of written comments is July 5, 2023, by 5:00 p.m. EDT. Written public comments should be submitted through the meeting web page. Persons submitting written comments should