

PARTNERSHIP ARRANGEMENT BETWEEN THE UNITED STATES FOOD AND DRUG ADMINISTRATION AND THE PACIFIC ISLAND HEALTH OFFICERS ASSOCIATION REGARDING COOPERATION FOR ACTIVITIES OF MUTUAL INTEREST

The United States Food and Drug Administration (FDA), and the Pacific Island Health Officers Association (PIHOA) (collectively “the Partners”) recognize the importance of timely and effective communication and collaboration in the promotion and protection of public health.

I. PURPOSE AND SCOPE

The Partners share a common interest in developing strong regulatory systems through sharing expertise, information, and technology to benefit FDA and PIHOA member U.S. Affiliated Pacific Islands (USAPI) and their populations by helping to ensure the safety of foods and cosmetics; and the safety and effectiveness of medical products imported into the United States.

II. AREAS OF COOPERATION

The Partners share a common interest in strengthening collaborations and communications, and optimizing use of resources to promote and protect public health through supporting collaborative partnerships in the following areas:

- Enabling and supporting the appropriate regulatory oversight provided by FDA and PIHOA member USAPIs’ regulatory systems through collaborative work and efficient use of resources
- Promoting more efficient and flexible use of regulatory resources through the sharing and mutual acceptance of data, where appropriate and in accordance with information sharing laws and regulations of the Partners and PIHOA member USAPI, while respecting the sovereignty of PIHOA member USAPI
- Promoting greater global alignment of regulatory approaches and technical requirements based on international standards and best practices
- Leveraging, where appropriate, existing PIHOA member USAPIs’ regulatory systems and avoiding duplication of efforts where possible
- Promoting a strong public health work force to ensure the safety of imported products

The activities intended to be planned and performed under this Partnership may include, but are not limited to, the following activities:

- A. *Investigatory Coordination and Communication:* This Partnership is intended to help ensure the safety of imported foods, cosmetics, and medical products through coordinated investigatory activities that may encompass, but are not limited to:
- Conducting and coordinating joint import operations to support common goals in protecting public health

- Optimizing use of personnel, equipment, and facilities to reduce duplication of effort
- Providing operational support and assistance within each Partner’s and PIHOA member USAPIs’ regulatory authority
- Enhancing electronic networking and communications to ensure rapid sharing of critical information through the Pacific Region
- Conducting and coordinating prompt and effective response operations during imported medical product emergencies, as well as foodborne illness outbreaks caused by imported food.

B. Training: This Partnership aims to enhance the proficiency of staff related to import oversight through activities that may encompass, but are not limited to:

- Training opportunities to enhance uniformity, competency, communication, and cooperation
- Developing, utilizing, and sharing of training resources
- Providing awareness of regulatory changes, health policy development, knowledge dissemination, communication enhancements, health services, and research activities
- Using integrated training faculty, when feasible, to best utilize expertise and increase communication and mutual understanding

C. Education, Information Sharing, and Community Outreach: This Partnership aims to support information sharing, knowledge exchange, and capacity-building activities to support PIHOA member USAPIs’ efforts to engage and inform industry and the public through activities that may encompass, but are not limited to:

- Developing approaches, processes, and tools to facilitate the exchange of scientific, technical, and regulatory information
- Increasing understanding of regulatory tools, standards, guidelines, and best practices that help ensure the safety of imported foods, cosmetics, and medical products throughout the supply chain and encouraging harmonized practices
- Collaborating and sharing technical information on the application of current Good Laboratory Practice, Good Regulatory Practice, Good Manufacturing Practice and Good Aquaculture Practice to monitor and enhance compliance activities, within current regulatory authorities
- Increasing understanding of food safety issues related to pathogens, contaminants, and toxins; and issues related to unapproved or counterfeit drugs

III. RESPONSIBILITIES OF THE PARTNERSHIP

FDA:

FDA intends to coordinate import activities, provide education, and make temporary loans of equipment to improve the overall quality of import operations within the PIHOA member USAPI, pending resource availability in accordance with the applicable laws,

regulations, and policies of the United States.

PIHOA:

PIHOA is a non-profit organization that is governed by and supports the collective interests of United States territories in the Pacific Region and other Pacific Island members that are independent nations. PIHOA includes the chief health officials of the five U.S.-Affiliated Pacific Islands (USAPI) which consists of two U.S. territories, which are American Samoa (AS) and Guam; and three Freely-Associated States (FAS), which are the Federated States of Micronesia (FSM), the Republic of the Marshall Islands (RMI), and the Republic of Palau. PIHOA's mission is to improve the health and wellbeing of the Pacific communities it serves by providing, through consensus, a unified credible voice on health issues of regional significance. PIHOA's mission is achieved through regional advocacy and policymaking, technical assistance and systems strengthening, resource mobilization, and partner engagement and coordination. Given PIHOA's unique role and position in the USAPI jurisdictions, under this Partnership, PIHOA intends to support FDA engagement through information-sharing and leveraging USAPI local and regional networks.

IV. CONFIDENTIALITY

In any activities under this Partnership, Partners should not share any non-public information, including confidential commercial information, financial information, or trade secret information obtained by or provided directly to Partners from a third party, subject to applicable law. The Partners intend that, if exchange of non-public information is sought, it is expected to be done on a confidential basis under suitable information sharing arrangements to be completed by the Partners under applicable law.

V. NON-BINDING

The Partners intend for all activities carried out pursuant to this Partnership to be conducted in accordance with the applicable laws, regulations, and policies of the United States, PIHOA and PIHOA member USAPI and to be subject to the availability of personnel, resources, and available funds. This Partnership does not create and is not intended to create any binding obligations under international or domestic law.

VI. DURATION AND PROCESS

The activities under this Partnership Arrangement may commence upon signature by both Partners and may continue for five (5) years. This Arrangement may be modified and/or renewed by mutual written decision of the Partners and may be discontinued by either Partner. Either Partner may discontinue this Arrangement at any time after giving 30 days' written notice to the other Partner.

VII. POINT OF CONTACT

Each Partner intends to designate, within 30 (thirty) calendar days after signing this Partnership Arrangement, a primary Point of Contact (POC) for itself. Designated POCs will be responsible for: (1) coordinating and organizing meetings between the Partners; (2) disseminating information received to the applicable Partner’s components and PIHOA member USAPI, as appropriate and permitted under applicable laws; (3) preparing proposals for collaboration to present to the applicable Partners’ and PIHOA member USAPI leadership; (4) collating and conveying strategic priorities and other urgent issues to applicable Partners’ and PIHOA member USAPIs’ leadership; (5) providing education and information on context-appropriate best-practices (6) developing and implementing any working plans, (7) preparing agendas; and (8) recording meeting highlights as necessary and appropriate.

UNITED STATES FOOD AND DRUG
ADMINISTRATION (FDA):

PACIFIC ISLAND HEALTH OFFICERS
ASSOCIATION (PIHOA):

_____/s/_____

_____/s/_____

Mark Abdo
Associate Commissioner
Office of Global Policy and Strategy

Gaafar Uherbelau
President, PIHOA Board of Directors
Minister of Health and Human Services
Republic of Palau Ministry of Health and
Human Services

Date: 7 October 2024

Date: 20 November 2024

The United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
United States of America

Pacific Islands Health Officers Association
Pacific Guardian Center
Makai Tower
733 Bishop Street, Suite 1820
Honolulu, HI 96813