FDA FACT SHEET

PARTNERSHIP AGREEMENTS

Program Description

- Partnership Agreements (PAs) are formal written documents that clearly define specific goals, activities and responsibilities of each partner with no obligation of fiscal resources (as required in contracts, grants, and cooperative agreements). Agreements are not legally binding, confer no legal obligation on either partner, and may be revised or terminated at any time.
- PAs are a subset of MOUs and are publicly posted on FDA's Memoranda of Understanding Website: https://www.fda.gov/about-fda/partnerships-enhancing-science-through-collaborations-fda/fda-memoranda-understanding.

Intended Outcomes

- PAs provide the tools and resources to enable FDA to work with regulatory partners to build systems that complement national uniformity of regulated products.
- Domestic Mutual Reliance (DMR) PAs are designed to capture engagement that work toward a seamless partnership that enables FDA and states with comparable regulatory public health systems, as trusted partners, to fully rely on, coordinate with, and leverage one another's work, data, and actions to achieve the public health goal of a safer national food supply.
- PAs seek to achieve maximum protection of consumer safety without duplication of regulatory activities among the FDA and implementing partners.
- Both generic and DMR PAs have the option of creating a supporting strategic plan to detail activities conducted by partners for the duration of the agreement.
- Meaningful metrics are tailored to each PA which annually evaluate program outputs and outcomes and measure success.

Program Metrics

- Current number of active agreements: (2)
    - MOU 225-20-007 Partnership Agreement Between U.S. Food and Drug Administration and the Alaska Department of Environmental Conservation: https://www.fda.gov/about-fda/domestic-mous/mou-225-20-007
    - MOU 225-21-010 Partnership Agreement Between U.S. Food and Drug Administration and The Utah Department of Agriculture and Food Division of Regulatory Services: https://www.fda.gov/about-fda/domestic-mous/mou-225-21-010

Success Stories

- **The Alaska Department of Environmental Conservation (ADEC) (renewal)**
    - This project developed radionuclide capability in the state of Alaska which has been beneficial both for routine annual radionuclide monitoring but more importantly for capacity in emergency response, if needed. Additionally, the Food and Drug Administration and Alaska Department of Environmental Conservation have annually been monitoring coastal finfish samples in response to the Fukushima event at the request of the public and the Fukushima Interagency Workgroup.ADEC has develop and published a list of finfish of concern. ADEC's activities are posted at: https://dec.alaska.gov/eh/radiation/.This partnership experienced success from 2016- 2019 and was renewed and expanded for the period 2020-2023.
- **The Utah Department of Agriculture and Food Regulatory Services (UDAF)**
    - UDAF formalized a domestic mutual reliance PA in April 2021. This PA provides a commitment for FDA HAF-W4 and UDAF to work together, as trusted partners, to establish domestic mutual reliance for the regulatory oversight of human food for which both participants have statutory responsibilities. Key areas of DMR include inventory reconciliation, data sharing, work planning, training of field staff, and exploring ways to support collaborative inspection, compliance, enforcement, and corrective action.

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The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, and products that give off electronic radiation, and for regulating tobacco products.