Resolution I: Collaboration with the U.S. Food and Drug Administration

USP will increase communication and collaboration with the U.S. Food and Drug Administration (FDA) to promote alignment with FDA’s regulatory and scientific policies from the inception of the standards planning and development process. USP will work with FDA, industry, and other stakeholders to increase understanding of the regulatory impact of such proposals.

USP continues to identify and embrace effective and impactful approaches for collaborating with the FDA and aligning with its strategic vision — and for reaching our shared goals of supporting innovation, science and access to quality medicines, dietary supplements and foods. Our ongoing discussions with the FDA and other partners address how we can advance the FDA’s public health mission and contribute to a modern system that protects consumers and patients.

In FY 2019 USP strengthened existing collaborations and developed new collaborations and dialogue with the FDA in key focus areas such as compounding, dietary supplements, innovation in nutrition, complex generics, approaches to mitigate misuse and abuse of opioids, approaches to safeguard the quality of opioids in the supply chain, generics access (Drug Competition Action Plan), and information sharing.

We convened meetings with the FDA’s senior leadership to explore ways that USP compendial standards, information, resources and tools can be updated or revised to help facilitate industry development of important generic medicines.

To facilitate future standards-setting work, we have convened meetings with FDA leadership to enhance compendial-related processes and to promote appropriate and effective sharing of information critical for standards development.

These efforts were supported by USP’s US Public Policy and Regulatory Affairs team members, who leveraged their regulatory experience to facilitate the development of key FDA-focused areas. The team built on existing relationships and forged new links to support compendial processes, policy and science.

USP will continue to actively engage with the FDA, industry and other stakeholders to facilitate the development of and access to quality medicines, promoting shared priorities and advancing positive health outcomes for consumers and patients. We are committed to continue working with the FDA and to exploring other mechanisms that enhance our ability to make a meaningful impact on public health.

Key Accomplishments

- Developed collaborations with the FDA and stakeholders in key public health-related focus areas, including innovative approaches for generics access and the opioid crisis
- Expanded relationships with FDA leadership across the agency to help support shared priorities and to enhance collaborations.
- With FDA leadership support, enhanced compendial-related processes and increased sharing of information critical for standards development
- Strengthened the U.S. Public Policy and Regulatory Affairs team — leveraging its regulatory experience to support compendial processes, policy and science