# USP and FDA Working Together to Protect Public Health

## About USP

The U.S. Pharmacopeial Convention (USP) is an independent, nonprofit organization that safeguards the public's health by developing quality standards for medicines, dietary supplements and food ingredients.

## USP-FDA Shared History and Mission

The USP-FDA relationship dates back to the 1906 Pure Food and Drug Act, which deemed the United States Pharmacopeia and the National Formulary official compendia under federal law.

## How USP and FDA Work Together

USP and FDA maintain official contact through a number of established channels:

- Five FDA centers and the Office of the Commissioner have established delegates at USP's Convention, the top leadership body of our organization.
- USP staff maintain executive-level contacts with FDA leadership and routine contacts with FDA's Compendial Operations and Standards Branch through quarterly meetings.
- More than 100 FDA staff participate as government liaisons on USP's Expert Committees and Expert Panels, the scientific bodies that develop and revise USP's written and physical standards.

Government liaisons represent FDA opinions and viewpoints (as opposed to other USP volunteers, who represent their own opinions rather than their employers') at public USP meetings such as the Expert Committee Meetings, Expert Panels and Stakeholder Forums.

## The Importance of USP-FDA Collaboration

FDA-USP collaboration is essential to ensure appropriate quality standards and, where applicable, standards that reflect FDA-approved product quality standards.

The FDA Office of Regulatory Affairs/USP Cooperative Research and Development Agreements enable USP and FDA to collaborate on protocols and work plans that impact the effective development of up-to-date monographs and nomenclature.

FDA and USP work together to identify areas for monograph or general chapter development where there is a need for quality issues to be addressed. Our interactions lead to a more efficient standards development process.

## USP's Role Under the Federal Food, Drug and Cosmetic Act

USP standards are an integral part of the patient safety framework:

- The Federal Food, Drug and Cosmetic Act (FDCA) expressly recognizes USP quality standards for medicines.
- Under the FDCA, USP standards are binding for dietary supplement manufacturers that label their products as compliant with USP specifications.
- FDA has issued more than 200 regulations for food substances that incorporate USP's *Food Chemicals Codex* specifications by reference.

Today our compendial standards remain connected to FDA provisions in the FDCA and other consumer protection laws, regulations and guidance that have been part of the important safeguards that make medicines, dietary supplements and food ingredients in the U.S. among the safest in the world.

## More Information

Learn more at **usp.org.**