



Resolution

Year 1 Resolution Update: Cannabis

Resolution

USP will leverage its scientific expertise and convening power to collaborate with stakeholders and develop fit-for-purpose scientific resources and solutions that will help address quality-related concerns as well as support additional scientific research on cannabis, cannabis-derived products, and cannabis-related compounds.

Alignment with USP's Mission

This Resolution encourages USP to continue its history of providing scientific and technical guidance for products used by consumers to help protect patient safety and public health. This is relevant for cannabis and related products due to their widespread use and the uneven regulatory environment across the U.S.

Year 1 Update

Key progress areas over the past fiscal year include:

Collaborating on Cannabis Quality – USP is driving conversation as a thought leader on quality through the following collaborative efforts:

- ▶ USP participated in meetings with industry, other standards development organizations, and stakeholders on the

importance of cannabis quality standards for public health, as well as on the appropriate quality attributes. In addition, USP engaged U.S. state and international regulators following our publication of quality attributes for cannabis inflorescence in the *Journal of Natural Products* with the goal that these attributes will be utilized by regulatory bodies.

- ▶ Voluntary consensus standard organization ASTM International (formerly known as the American Society for Testing and Materials) subsequently adopted USP Cannabis Expert Panel recommendations for cannabis inflorescence quality attributes as a part of industry guidelines. Beyond use for cannabis inflorescence, the quality attributes are also fit for use in analysis of hemp extract oil matrix, as was determined through USP's participation in a National Institute of Standards and Technology proficiency test program.
- ▶ USP provided comments on FDA's draft guidance on cannabis quality for clinical research applications, and to multiple state regulators on proposed quality controls. USP also provided comments in response to the Cannabis Administration and Opportunity Act discussion draft, including the recommendation that legally marketed products containing cannabis and

hemp-derived substances like cannabidiol (CBD) should adhere to science-based public quality standards.

Quality Specifications for CBD – USP’s Botanical Dietary and Herbal Medicine Expert Committee and its Cannabis Expert Panel developed quality specifications for CBD as a drug substance. These include analytical methods and acceptance criteria for identification, quantitative estimation supported by suitable reference standards, and limits on CBD contaminants. Because CBD may be purified from the cannabis or hemp plant, or chemically produced, suitable methods were provided to analyze related compounds and impurities derived from hemp as well as synthetic processes.

Quality Specifications for *Food Chemicals Codex Monographs* – The USP Food Ingredients Expert Committee has published proposed monographs for hemp seed oil and hemp seed proteins. FDA had no questions about the conclusion that the substances are “generally recognized as safe” (GRAS) food ingredients under the conditions identified as part of the FDA GRAS notification process. Both proposed monographs contain specifications and test methods for identification, purity, and limits on impurities including tetrahydrocannabinol and CBD. If finalized, the monographs will be the first

public compendial standards for cannabis-derived food ingredients in the world.

Planned for Year 2

- ▶ USP will continue to work on standards development. This will include working through the Cannabis Expert Panel on specifications for cannabis and hemp extracts, suitable nomenclature, definitions, and quality specifications. USP will also evaluate the need for Expert Panel or other work processes to address synthetic CBD health hazards.
- ▶ USP will continue to monitor the evolving regulatory landscape, engage on development of general draft comments for discussions with U.S. federal and state regulators, and seek interactions with global regulators and industry to advance adoption of USP informational resources.
- ▶ USP will continue its work on capability building in concert with other standards-setting organizations, advance education and training, and proficiency testing based on public standards.

Contact

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