



## Checklist for Submissions to the *Food Chemicals Codex (FCC)*

This checklist can be used to prepare submission packages for new monographs and proposals for revisions to existing *FCC* monographs. For more detailed information, please consult the *Guideline for Submission of A New Food Ingredient Monograph to the Food Chemicals Codex* and the *Guideline for Submission of Revisions to the Food Chemicals Codex* available on our website at <http://www.usp.org/fcc/submitMonographsRevisions.html>.

### **Regulatory Status**

- Approved Food or Color Additive (US)
- Successful GRAS Petition (US)
- Successful GRAS Notification (US)
- Self-determined GRAS (US)
- Code of Federal Regulations (CFR)* Reference
- International Regulatory Approval

### **Monograph Content**

- Proposed Title
- Synonyms
- Chemical Information (formula, formula weight, structure, FEMA/CAS/INS numbers, etc.)
- Description (color/appearance, source, method of manufacture, general solubility or physical characteristics, components, added ingredients, etc.)
- Function (Use existing *FCC* categories or refer to Codex Alimentarius Class Names and International Numbering System for Food Additives (CAC/GL 36-1989) or the U.S. Code of Federal Regulations (21 CFR 170.3(o).))
- Packaging & Storage (See General Provisions in *FCC* for guidance. Include any special handling instructions.)
- Identification tests and specifications
- Assay test(s) and specification(s)
- Impurities test(s) and specification(s)
- Specific test(s) and specification(s)

**Note:** It is not a requirement to submit a draft monograph or revision written in the *FCC* style, but it is USP's preference that all monograph elements be present. For revisions, only the monograph contents to which revisions are proposed must be submitted.



## Checklist for Submissions to the *Food Chemicals Codex (FCC)*

### Supporting Data

- Include validation data/reports. This is required for any procedure that is submitted that is not already a compendial (*FCC, USP-NF, JECFA, EP, etc.*) method. For further information on method validation requirements, refer to the *General Information* section of the *FCC*.
- Include representative spectra (e.g. IR, UV) for Spectrophotometric procedures.
- For chromatographic procedures:
  - Include representative chromatograms (e.g. standard solution, sample solution, system suitability solution, related compounds, etc.)
  - Include the brand name of the chromatographic column used for the validation.
- Include Certificates of Analysis (COA) for at least three production-scale batches of food grade product. If COAs are not available, data can be submitted in a summary table or other convenient format. The data should indicate that the product meets all of the specifications proposed in the monograph (or revision).

### Labeling Information

- Include monograph-specific labeling requirements regarding safety and handling of the product.

### Reference Standards

- Please indicate if you are willing to donate the reference standard material(s) to support the proposed procedure(s). For further information on Reference Standard donation, see the *USP Guideline for Donors of Reference Standard Candidate Materials, August 2014 (version 2.2)* available on our website at:  
[http://www.usp.org/sites/default/files/usp\\_pdf/EN/referenceStandards/usp\\_reference\\_material\\_information\\_form.pdf](http://www.usp.org/sites/default/files/usp_pdf/EN/referenceStandards/usp_reference_material_information_form.pdf)

### Confidential Information

- Please mark all confidential information submitted to USP as “Confidential” to indicate that it is not to be disclosed to a third-party outside of USP. Please also note that *FCC* monographs are public standards that contain information intended to be used by all interested stakeholders.

This checklist supersedes any previous checklist issued by USP on Submission to the Food Chemicals Codex.