

Checklist for Submitting Requests for Revision to the *FCC*

This checklist can be used to prepare submission packages for new monographs and requests for revisions to existing monographs. For detailed information, please consult the *Guideline for Submitting Proposals for New Monographs to the Food Chemicals Codex* and the *Guideline for Submitting Proposals for 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)
- 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 preferable if all elements are present. For revisions, only the monograph contents to which changes are proposed must be submitted.

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 Suppliers of Reference Standard Materials, Sept. 12, 2008 (version 2.0)* available on our website at <http://www.usp.org/USPNF/submitMonograph/subGuide.html>.