Checklist for Submitting Requests for Revision to the USP-NF
For New and Existing Dietary Supplement Monographs

This checklist can be used to prepare submission packages for new dietary ingredient/supplement monographs and requests for revisions to existing dietary ingredient/supplement monographs. For detailed information, consult the Guideline for Submitting Requests for Revision to the USP-NF available http://www.usp.org/USPNF/submitMonograph/subGuide.html.

☐ Approval Status
Indicate which of the following applies to the dietary ingredient or dietary supplement (dosage form)
(a) was marketed by your company before 1994 as a food or dietary supplement,
(b) A New Dietary Ingredient (NDI) was submitted and filed by FDA with No Objections from the agency, or
(c) A GRAS notice was submitted to FDA and filed by the agency with No Objections.

☐ Monograph Content
Include the list of proposed tests, procedures and acceptance criteria for the identification, composition/strength, impurities, specific tests, and additional requirements (such as performance characters of dosage forms).
Note: It is preferable, although not required to submit a draft monograph or revision in the USP-NF format. Following the USP format will draw attention to the details necessary to be addressed for the success of submission.

☐ Description of the ingredient
For the proposed article, provide:
• Chemical names and structures of the active constituents or marker compounds, with their corresponding formulas, molecular weights, and CAS registry numbers.
For dietary supplements (finished dosage forms), indicate:
• Performance characteristics
• Product Master Formula indicating quantity of ingredients and excipients, overages and relative proportions.

☐ Supporting Data
Include the following:
• Validation data
  This is required for any procedure developed and validated by the sponsor company.
  Typically includes the following as validated per General Chapter <1225> Validation of Compendial Methods and current FDA/ICH guidelines:
  - chromatographic procedures for Identification, Assay or Composition of the active or marker principles, and
  - tests for Contaminants
• Validation or verification data
  Include any data available for tests performed according to general chapter tests (e.g., residue on ignition, water, elemental impurities, etc.).
• Also include any validation or verification data available for official methods from other compendia.
• Representative spectra for spectroscopic and spectrometric procedures
• Chromatographic procedures:
  - Include representative chromatograms (e.g., standard solution, test solution, system suitability solution, related compounds, etc.)
  - Include the complete information of the chromatographic column used for the validation
• Contaminants:
  - Provide the data and procedures for elemental impurities, residual solvents, microbial levels for as many batches of the material as available
• Certificate of Analysis (COA):
  - Include COAs for at least three production-scale lots/batches
  - If COAs are not available, data may be submitted in a summary table, however the submitters are strongly encouraged to supply official release data
  - Provide disintegration or dissolution test procedures and data for dosage forms.
• Manufacturing Process
  - Include a brief scheme or flow chart of the manufacturing process. Comment if any processing steps are known to effect degradation or loss of active principles or analytical markers

☐ Packaging and Storage
• Include packaging and storage recommendations (e.g., preserve in tight containers and store at controlled room temperature)
• Include any special handling instructions (e.g., do not freeze, etc.)

☐ Labeling Information
   Indicate specific labeling requirements regarding safety and handling of the product

☐ Description and Solubility Information
   Proposed dietary ingredient/supplement monograph should include a description and solubility entry (e.g., white to off-white powder freely soluble in methanol)

☐ Reference Standards
• Indicate willingness to donate the reference standard material(s) to support the monograph development
• For additional information, see the Guideline for Donors of USP Reference Standard Candidate Materials available on our website at http://www.usp.org/USPNF/submitMonograph/subGuide.html.