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.