

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 ingredients, indicate:

- Latin binomial(s) including current authorship
- Plant part(s) (i.e., aerial parts, root, leaf, flower, rhizome, etc.), plant product (e.g., resin, oleogum-resin), and where applicable the processed form. For the latter, include the detailed processing flowchart, indicate solvents used, typical extract ratios (ratio of the finished extract to the starting material), and specify the typical amounts of excipients and processing aides if used.
- Synonyms and common names

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
- For botanical materials, also include:
 - Description of macroscopic and microscopic details. Color photographs are preferred.
 - List of potential adulterants (confounding materials)
 - Fingerprinting: Chromatographic and spectroscopic data for comparison with possible related materials or adulterants
- 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 as many batches of material as available, in particular to capture seasonal and geographical variation, processing variability, and to support the proposed specification ranges
 - 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

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>.