Checklist for Submitting Requests for Revision to the *USP–NF*
for New and Existing Small Molecules Monographs

This checklist can be used to prepare submission packages for new **small molecules** monographs and requests for revisions to existing **small molecules** monographs. For detailed information, consult the *USP Guideline for Submitting Requests for Revision to USP–NF*, available on our website.
The information below is typically listed in the 3.2.S. for drug substances and 3.2.P. for drug products in the approved application (eCTD).

- **Approval Status**
  - ☐ Finished dosage form:
    - Indicate approval status (e.g., approved, OTC or OTC switch, etc.)
    - Provide the FDA letter of approval (if available)
  - ☐ Drug substance monograph:
    - Indicate if it has been included in an approved application
    - Provide the ANDA number or a letter of authorization (DMF holders)
  - ☐ Application pending FDA approval:
    - Supply filing letter or tentative approval letter from the FDA (if available)
    - For more information, see *Pending Monographs Guideline*

- **Monograph Content**
  Note: It is not a requirement to submit a draft monograph or revision written in USP–NF style.
  - ☐ Methods/Procedures:
    - Include all proposed tests and analytical procedures (see *Required Supporting Data* section).
    - Include brand/grade of all reagents used in the analytical procedures
  - ☐ Shelf-life acceptance criteria
  - ☐ For revisions of an existing monograph:
    - Provide rationale for the proposed changes

- **Chemical Information**
  For the proposed article (e.g., drug substance, drug product) and each known impurity and/or degradation product, include:
  - ☐ Chemical name(s)
  - ☐ Chemical structure
  - ☐ Molecular formula
  - ☐ Molecular weight
  - ☐ CAS no. (if known)

- **Validation/Verification Data**
  - ☐ Validation data:
    - Typically applies to chromatographic procedures for Assay and Organic Impurities tests validated per Validation of Compendial Procedures <1225> and current FDA/ICH guidelines.
  - ☐ Verification data:
    - Include any data available for general chapter tests (e.g., Residue on Ignition, Water, Elemental Impurities, etc.).

- **Required Supporting Data**
  - ☐ Stability data for the drug substance/product
  - ☐ Certificates of Analysis (COAs)
    - Include COAs for at least three production-scale lots/batches. If COAs are not available, data can be submitted in a summary table or other convenient format.
  - ☐ Spectrophotometric procedures:
    - Include representative spectra (e.g., IR, UV)
  - ☐ Chromatographic procedures:
    - Include representative chromatograms (e.g., standard solution, sample solution, system suitability solution, peak identification solution, etc.)
    - Include the brand name and the specifications of the chromatographic column used for the validation
    - Include forced degradation data to support stability-indicating procedures

- **Dissolution/Disintegration/Drug release tests (if applicable)**
  See *Guideline on Dissolution / Drug Release / Disintegration Tests in USP Monographs*
  - ☐ Include a copy of the product's specification, a copy of the FDA approval letter (the letter issued by the FDA Bioequivalence group), and results from at least three batches if available (any type of batch)
  - ☐ Include a summary of the justification for the selection of the test conditions (medium, apparatus, etc.)
  - ☐ Include the dissolution analytical method and validation report

- **Additional Requested Data**
  - ☐ Packaging and Storage:
    - Include packaging and storage recommendations (e.g., preserve in tight containers and store at controlled room temperature)
    - Include special handling instructions (e.g. store under nitrogen, do not freeze, etc.)
    - For proposed finished dosage form monographs, include a copy of the approved package insert
  - ☐ Labeling Information:
    - Include monograph-specific labeling requirements regarding safety and handling of the product (e.g., must be diluted before use, must be shaken before use, indicate if it is of plant or animal origin, etc.)
  - ☐ Include a description and solubility entry (for proposed drug substance monographs)

- **Reference Standards**
  - ☐ Indicate, in writing, the organization's ability to donate the reference standard material(s) to support the standard development
    - Typical bulk donation amounts are 250 g for API and 10-25 g for Impurities
    - If relevant reference material cannot be provided in the estimated quantities above, USP may need to look for an alternate source, which may delay the development of the standard.
  - ☐ For additional information, see the *USP Guideline for Donors of USP Reference Standard Candidate Materials* available on the USP website.