

RULES AND PROCEDURES OF THE 2010–2015 COUNCIL OF EXPERTS

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1. GENERAL

1.01 Governance and Authority

As set forth in Article VII, Section 1 of the Bylaws, the Council of Experts and its Expert Committees are responsible for determining and approving content of the official compendia and other authorized publications, including but not limited to translations and line extensions of the *USP-NF*, and any other information that may be published by or on behalf of the Council of Experts or an Expert Committee from time to time. In order to fulfill these responsibilities, the Council of Experts is authorized under Article VII Section 5 of the Bylaws to make such Rules and Procedures, not in conflict with the Bylaws, that are sufficient to ensure the accuracy and adequacy of the content of the *USP-NF* and other authorized publications, and to provide for adequate notice and opportunity for public comment and full and impartial consideration of all proposed changes to such publications. These Rules and Procedures of the Council of Experts (Rules) govern the activities of the Council of Experts and those bodies related to the Council of Experts, including the Executive Committee, Expert Committees, Expert Panels, Stakeholder Forums and Project Teams. From time to time USP staff may also issue Guidelines publicly accessible on the USP website (e.g., Guidelines for *USP-NF* Submissions; Non-U.S. and Pending Monographs, Accelerated Revisions, and others) consistent with the Rules to promote transparency of USP's internal processes and procedures.

1.02 Procedural Questions

On procedural questions, the current edition of *Robert's Rules of Order, Newly Revised* shall prevail where the Rules are silent.

1.03 Adoption and Amendment

Prior to adoption by the Council of Experts, these Rules shall be submitted to the Governance Committee of the Convention and the Board of Trustees for review and approval as provided in Article VII, Section 5 of the Bylaws. These Rules may be amended at any time during the cycle, provided that any proposed amendment also shall be submitted to the Governance Committee and the Board for review and approval prior to adoption.

2. STANDARDS OF CONDUCT

2.01 Code of Ethics

Members of the Council of Experts, Expert Committees and Expert Panels shall be required to adhere to the USP Code of Ethics, copies of which are available on USP's website.

2.02 Representation

Members of the Council of Experts, and Expert Committees, serve USP as individual experts; they do not serve any outside interest. A member of the Council of Experts or an Expert Committee shall not use his or her membership in any way that is, or appears to be, motivated by private gain or any outside interest. A member of an Expert Panel may serve an outside interest provided such interest is disclosed pursuant to Section 6.05 of these Rules.

2.03 Conflict of Interest

- (a) General. Pursuant to Article VIII, Section 1, of the Bylaws and the Conflict of Interest Policy in the Code of Ethics, all members of the Council of Experts and its Expert Committees ("CoE/EC Expert") shall adhere to the Conflict of Interest provisions set forth in this section. Expert Panel members are subject to the Conflict of Interest requirements contained in Section 6.05 of these Rules. As used in this section "Conflict of Interest" includes, but is not limited to, any matter in which a CoE/EC Expert has a direct financial interest or any other personal interest of any kind which would preclude or appear to preclude such individual from exercising impartial judgment or otherwise acting in the best interest of the Convention. It is the responsibility of each CoE/EC Expert to inform the USP Executive Secretariat, the Scientific Liaison(s), and/or the chairperson of a particular Expert Committee should a situation arise in which he or she has or may have a Conflict of Interest.
- (b) Recusal. No CoE/EC Expert shall vote nor take part in the final discussion or deliberation of any matter in which he or she has a Conflict of Interest. An Expert Panel member may participate in deliberations or recommendations regarding matters in which he or she has a Conflict of Interest provided disclosure of a Conflict of Interest is made pursuant to Section 6.05 of these Rules.
- (c) Assignment of Work. No CoE/EC Expert shall be assigned the primary responsibility to work on an issue or question in which he or she has a Conflict of Interest. He or she may, however, provide relevant scientific information and may participate in discussions regarding such issue or question; providing, however, that final discussion, deliberation and vote on such issue or question shall be conducted without such member present. Expert Panel members who have a Conflict of Interest may be assigned work on matters in which they have a Conflict of Interest provided disclosure of such Conflict of Interest is made pursuant to Section 6.05 of these Rules.
- (d) Conflict of Chair. In the case where the chairperson of an Expert Committee has a Conflict of Interest, the vice chairperson will serve. If the vice chairperson also is conflicted, a designated non-conflicted member shall lead the discussions. The chairperson of an Expert Panel that has a Conflict of Interest may continue to serve in that capacity provided disclosure of such Conflict of Interest is made pursuant to Section 6.05 of these Rules.

2.04 Conflict of Interest Statements

- (a) Requirement. Each member of the Council of Experts, the Expert Committees, and Expert Panels shall submit to USP a statement of all employment, professional research, organizational memberships, and other interests that could result in a Conflict of Interest. The Conflict of Interest statement shall be updated by the member as necessary to keep it current or as requested periodically by USP. Except as specified in Section 2.05 below, the information provided in Conflict of Interest statements shall be kept confidential.

- (b) Failure to Submit Statement. If a member of the Council of Experts, Expert Committee, or Expert Panel fails to submit a Conflict of Interest statement, that member will not be allowed to participate in Expert Committee or Expert Panel activities until such statement is submitted.

2.05 Identification and Resolution of Conflict Issues.

- (a) USP Responsibility. USP staff, together with the chairperson of an Expert Committee or Expert Panel, shall review Conflict of Interest statements on an ongoing basis to identify potential Conflicts of Interest. Where a potential Conflict of Interest arises, the chairperson and USP staff shall work with the individual, and if necessary or in the case of Conflicts of Interest involving a member of the Council of Experts, the Chair of the Council of Experts and the USP Executive Secretariat, to resolve the matter. In the case of an Expert Panel member, the chairperson and USP staff will assure any such conflicts are adequately disclosed to the Expert Panel membership. If the matter cannot be resolved, the question shall be referred to the USP Secretary for resolution. The minutes of any meeting at which a Conflict of Interest issue has been addressed shall reflect disclosure and resolution of such issue, including any recusal of a CoE/EC Expert due to conflict of interest.
- (b) Expert Responsibility. Any CoE/EC Expert or member of an Expert Panel who believes or should have reason to believe that he or she may have a Conflict of Interest shall notify USP staff and the chairperson of the Expert Committee or Expert Panel, as applicable, prior to any work on or discussion of the matter in question, and such issues shall be resolved as described in Section 2.05(a) above.

2.06 Confidentiality

- (a) Obligation to Maintain Confidentiality. Each CoE/EC member shall maintain the confidentiality of all information gained in the course of his or her activities as a CoE/EC Expert, and shall not use or disclose such information for any purpose, unless such information is already publicly available. In case of doubt as to whether information is deemed confidential, the information shall be treated as confidential until otherwise indicated by the USP Executive Secretariat or USP Secretary. Expert Panel members are obligated to maintain confidentiality of materials in accordance with Section 6.05(b) of these Rules.
- (b) Confidentiality Agreement. Each CoE/EC Expert and Expert Panel member shall sign a confidentiality agreement reflecting the confidentiality obligations set forth in Section 2.06(a). If a CoE/EC Expert or Expert Panel member fails to submit a confidentiality agreement, that member will not be allowed to receive any confidential information or participate in the Council of Experts, Expert Committee or Expert Panel activities until such agreement is submitted.

3. THE COUNCIL OF EXPERTS

3.01 Chairperson

In accordance with Article IV Section 11 and Article VII of the Bylaws of USP, the Executive Vice President-Chief Executive Officer (EVP-CEO) or the EVP-CEO's designee shall serve as Chairperson of the Council of Experts (CoE Chairperson) and establish policies and Work Plans (as defined in Section 5.05 below), assign responsibilities, and otherwise direct the work of the Council of Experts and its Expert Committees. The CoE Chairperson shall chair all meetings of the Council of Experts and the Executive Committee. In the event of the temporary absence of the CoE Chairperson, the CoE Chairperson shall designate another person to act in his or her stead. The CoE Chairperson may also appoint USP staff members to act as scientific liaisons to Expert Committees ("Scientific Liaisons") to work on behalf of the CoE Chairperson to support and assist the Council of Experts and its Expert Committees in carrying out their Work Plans and other assigned responsibilities.

3.02 Election and Duties

The Council of Experts shall be elected in accordance with Article VII, Section 2 of the Bylaws. Each member of the Council of Experts shall chair an Expert Committee. In the event of a vacancy in the Council of Experts the Council of Experts shall appoint a replacement as provided in Article VII, Section 7 of the Bylaws. The chairperson of each Expert Committee shall meet with the CoE Chairperson on a regular basis to report progress against the established Work Plan, adjust tasks as appropriate, and discuss other matters relating to the Expert Committee.

3.03 Removal

A member of the Council of Experts may be removed for cause by the Board of Trustees, upon recommendation of the CoE Chairperson or the Executive Committee, as provided in Article VII, Section 2 of the Bylaws. As used herein, "cause" may include, but is not limited to, unprofessional conduct, inattention to duties, or failure to abide by USP's Code of Ethics or these Rules.

4. THE EXECUTIVE COMMITTEE

4.01 Composition

The Executive Committee shall be appointed by the CoE Chairperson pursuant to Article VII, Section 6 of the Bylaws. Unless sooner removed as provided herein, members of the Executive Committee shall serve a one year term and shall be eligible for re-appointment by the CoE Chairperson. Members of the Executive Committee may be removed by the CoE Chairperson at any time.

4.02 Function

The Executive Committee shall have those duties and responsibilities set forth in Article VII, Section 6 of the Bylaws, including providing advice to the CoE Chairperson on matters of general policy and receiving and ruling upon all appeals, and shall perform such functions as are specified in these Rules.

5. EXPERT COMMITTEES

5.01 Number of Committees

The Board of Trustees shall approve the number of Expert Committees in accordance with Article VII, Section 3 of the Bylaws. The CoE Chairperson, in consultation with the Council of Experts, may at any time during a current cycle recommend to the Board that additional Expert Committees be established to carry out the work of the Convention, in accordance with Article VII, Section 4 of the Bylaws. If approved by the Board, the chairs of such additional Expert Committees shall be appointed by a majority vote of the Council of Experts.

5.02 Election of Expert Committee Members; Removal and Vacancies

Members of each Expert Committee shall be elected by the Council of Experts. An individual may be elected to more than one Expert Committee. A member of the Council of Experts may be elected to serve as a member of any other Expert Committee. A member of an Expert Committee may be removed for cause by the CoE Chairperson, upon the recommendation of the Expert Committee chairperson, and cause shall have the meaning set forth in Section 3.03 above. In the event of a vacancy in an Expert Committee or if additional members are determined to be needed on any Expert Committee, the CoE Chairperson shall appoint new members.

5.03 Vice Chair

Each Expert Committee shall elect a vice chairperson to serve in the temporary absence of the chairperson. In the event of a permanent vacancy of the chairperson's office, the vice chairperson shall serve as chairperson until a new chairperson is appointed by the Council of Experts in accordance with Article VII, Section 7 of the Bylaws.

5.04 Expert Committee Work Plan

Each Expert Committee shall work with the CoE Chairperson and other USP staff to develop a work plan which sets forth the standard setting goals and objectives of the Expert Committee for the cycle (Work Plan). The Work Plan shall be revised as needed subject to the approval of the CoE Chairperson. The Work Plan and any revisions thereto shall be made publicly available. Reports of progress made under the Work Plan shall be provided to the CoE Chairperson and made publicly available on a regular basis.

5.05 Subcommittees

Expert Committees may form subcommittees to advance their work. A subcommittee is a group of members of a single Expert Committee assigned to perform a certain task of the Expert Committee. A joint subcommittee is a group of members from two or more Expert Committees assigned to perform a certain task of interest to such Expert Committees. A subcommittee or joint subcommittee may make recommendations to the Expert Committee responsible for a particular task or issue, but all decision-making authority shall be retained and exercised by the Expert Committee. A joint subcommittee shall only make recommendations to, and be directed by, one Expert Committee, which shall be designated by the CoE Chairperson, and exercise decision-making authority with respect to the task. Expert Committees not charged with oversight and decision-making authority shall be kept apprised of the work of a joint subcommittee by their members that have been assigned to the joint subcommittee.

5.06 Expert Consultations

From time to time, an Expert Committee (Requesting Expert Committee) may request that a CoE/EC Expert from another Expert Committee participate in the Requesting Expert Committee's meetings or other work in order to obtain additional expertise in a particular area. Such participating CoE/EC Experts shall not be deemed members of the Requesting Expert Committees or vote on any Requesting Expert Committee matter. An Expert Committee may also request assistance from an individual who is not a CoE/EC Expert to participate in discussions or review documents where such individual provides necessary expertise not available within the Council of Experts or Expert Committees. Such individual shall be required to sign a confidentiality agreement requiring that the confidentiality of all information provided to such individual be maintained.

6. EXPERT PANELS

6.01 Formation

The CoE Chairperson may form an advisory Expert Panel to provide additional expertise and perform an assigned task for a particular Expert Committee or Expert Committees. The CoE Chairperson shall appoint the members of the Expert Panel, who may be removed by the CoE Chairperson at any time. USP will seek the most qualified experts on a particular topic, and will work to assure broad and diverse membership. At least one member of the Expert Committee to which the Expert Panel reports shall be a member of the Expert Panel. Any Expert Committee member that becomes a member of an Expert Panel or participates at an Expert Panel meeting may do so only as a representative of USP. An Expert Panel will continue until its assigned task has been completed or until dissolved by the CoE Chairperson.

6.02 Chairperson, Charge and Scope

The CoE Chairperson shall appoint, and may remove at any time, the chairperson of an Expert Panel. The CoE Chairperson shall provide an Expert Panel with a specific charge, including scope of work (advisory only), deliverables, and timelines for completion of work, and dissolve such Expert Panel at the conclusion of the specified work. The task performed by the Expert Panel shall be consistent with the Expert Committee's Work Plan, unless the Expert Panel's task is deemed by the CoE Chairperson to be critical or a public health emergency.

6.03 Reporting Requirements.

The chairperson of the Expert Panel shall report on its progress as needed or as requested by the Expert Committee chairperson or the CoE Chairperson. The Expert Panel shall issue advisory recommendations to the Expert Committee upon the completion of its task, which shall be accompanied by a disclosure of Conflicts of Interest information identified under Section 6.05(a) below. Expert Panel members will strive to reach consensus on their compendial topic and are expected to complete their task within the specified timeframe, but are not required to achieve unanimity. Dissenting views of Expert Panel members may be expressed in writing and accompany the Expert Panel's advisory recommendations to the Expert Committee.

6.04 Joint Expert Panels

A Joint Expert Panel advisory to two or more Expert Committees may be established. However, the CoE Chairperson shall designate a lead Expert Committee responsible for the oversight of such Joint Expert Panel. In selecting members of a Joint Expert Panel and appointing a Chairperson, the CoE Chairperson shall consider the advice of the chairs of each involved Expert Committee. The formation, charge and reporting for the Joint Expert Panel shall be the responsibility of the lead Expert Committee.

6.05 Conflict of Interest and Confidentiality.

(a) Conflicts. Conflicts of Interest, as defined in Section 2.03, will not be a bar to participation on an Expert Panel or in any deliberations or recommendations of the Expert Panel, including voting, provided the Expert Panel member timely and adequately discloses any Conflict of Interest as required by Sections 2.03, 2.04 and 2.05 of these Rules to other members of the Expert Panel including the chairperson.

(b) Confidentiality. Expert Panel members are not necessarily obligated to maintain confidentiality of materials obtained and issues discussed during the course of the panel's task. However, confidentiality may be required in certain instances as identified by the Expert Panel Chairperson and USP staff including, but not limited to, protecting third party confidentiality obligations, preventing the premature disclosure of a standard, or maintaining the confidentiality of proprietary, business, or trade secret information.

7. USP-NF STANDARDS

7.01 Official Publication of *United States Pharmacopeia* or *National Formulary* Standards

The final approved text of a revision to the *United States Pharmacopeia (USP)* or *National Formulary (NF)* shall be published and distributed to the public via print and/or electronic means through the following vehicles: annual editions of the *USP-NF*, *Supplements* to the annual edition, *Interim Revision Announcements*, *Revision Bulletins* and *Errata*. Unless otherwise determined by USP, a revision that includes the use of a new USP Reference Standard shall not be published as final approved text until the required USP Reference Standard is available. All revisions shall become official six (6) months after publication, unless otherwise specified in the publication vehicle.

7.02 Accelerated Revision Processes

Accelerated revision processes are used to make revisions to the *USP-NF* official more quickly than through USP's standard revision process when necessary to correct errors, address patient safety issues, or resolve compliance issues. Such accelerated revisions, which include *Interim Revision Announcements*, *Revision Bulletins* and *Errata*, do not always require notice and comment and allow for a revision to become official prior to the next *USP-NF* or *Supplement*. Accelerated revisions may be used only in the circumstances described in USP's Guideline on the Use of Accelerated Processes for Revisions to the *USP-NF*, which is posted on USP's website.

7.03 High Impact Revisions

- (a) Design Phase. Prior to undertaking the development of or major revision to a standard that is expected to have a very broad impact on USP's stakeholders ("High Impact Revision"), USP shall employ a "design phase" approach involving USP, affected industry, FDA and other regulators, and other interested stakeholders such as practitioners and patients. USP shall consider using a workshop, a Web meeting, or other similar forum to bring all parties together to discuss: the scientific and public health issues to be addressed by the High Impact Revision; the proposed scope of the High Impact Revision; a proposed timeline for development of the High Impact Revision; and implementation considerations. Such discussion shall also consider whether one or more Expert Panels are necessary or desirable to advance the High Impact Revision. Based on this discussion, USP shall develop a "roadmap" for the High Impact Revision, which shall be communicated to stakeholders and shall guide USP's work on the High Impact Revision.
- (b) Prepublication of Proposed Standard and Outreach. USP will consider publishing proposals for High Impact Revisions in the form of a Stimuli article or in some other manner that will allow stakeholder input prior to publication of a formal proposal for notice and comment in *PF* as provided in Section 7.06 below. As a High Impact Revision is developed, USP will also consider other mechanisms for ongoing stakeholder dialogue, including webcasts and other outreach opportunities.
- (c) Delayed Implementation and Training. Based on stakeholder input and other considerations, USP shall determine the appropriate implementation date for a High Impact Revision. Delayed implementation dates will be considered in order to allow sufficient time for implementation by industry and regulatory authorities. USP will also consider the need for training and education during the implementation period to assist industry, regulators and others in understanding and determining how to implement the High Impact Revision.

7.04 International Harmonization

In USP's effort to harmonize the *USP-NF* with the *European Pharmacopoeia* and the *Japanese Pharmacopoeia* through the Pharmacopeial Discussion Group ("PDG"), any harmonized standard that has been agreed to by a designated representative of USP shall be approved by the relevant Expert Committee in order for such standard or information to be considered official or authorized or adopted by USP. If a standard has been harmonized, such a standard shall not be modified beyond the addition of locally applicable text without first obtaining agreement of the partners in PDG, unless it is determined by the CoE Chairperson and the Expert Committee that such modification is necessary in the interest of public health. In such case, the CoE Chairperson or his designee shall immediately notify the PDG partners and provide the reasons for making such changes.

7.05 Requests for Revisions

- (a) Submission of Requests for Revision. A Request for Revision is a proposal to revise the *USP-NF*, with either changed or new content. A Request for Revision must be submitted in accordance with the USP Guideline for Submitting Requests for Revision to *USP-NF*, available on USP's website, and may be refused if it does not substantially conform to the Guideline. Proposals to revise the *USP-NF* may also be initiated by Expert Committees or by USP staff.
- (b) Review of Request for Revision. All Requests for Revision shall be forwarded to the appropriate Scientific Liaison. The Scientific Liaison shall evaluate the relevancy, supportability, and urgency of the Request for Revision in accordance with established policies and procedures. The Scientific Liaison may initiate work on the Request for Revision or provide the Request for Revision to the relevant Expert Committee or Expert Panel for its recommendations.
- (c) Notice of Intent to Revise. If it is determined that revisions to a Monograph or General Chapter should be made, and upon request of any party, a Notice of Intent to Revise will be posted on USP's website indicating the changes to be made upon approval by the

relevant Expert Committee(s). Such changes shall be made through a Request for Revision and handled in accordance with the procedures described in these Rules.

- (d) Approved for Inclusion. As set forth in USP's Guideline on Drugs Approved for Inclusion, available on USP's website, upon the written commitment from a party to submit a Request for Revision, together with adequate supporting data and the bulk material required for any accompanying reference standard, USP may notify the Centers for Medicare and Medicaid Services (CMS) that such article has been "approved for inclusion" in the *USP-NF*. Such "approved for inclusion" status may be revoked at USP's discretion upon the party's failure to fulfill such commitment in a timely fashion.

7.06 Publication in the *Pharmacopeial Forum*

- (a) Publication in *Pharmacopeial Forum*. Except as provided in Section 7.02 above, all proposals for revisions to the *USP-NF* shall be published in the *Pharmacopeial Forum (PF)* for public review and comment. Unless otherwise determined by USP, a proposal that includes the use of a new USP Reference Standard shall not be scheduled for publication in *PF* until a suitable reference standard bulk candidate has been received by USP.
- (b) Public Notice; Consideration of Comments. Except as provided in Section 7.02 above, a period of at least ninety (90) days from the date of publication will be allowed for public review and comment. The time allowed for public comments shall be noted in the publication in the *PF*. For good cause shown, the CoE Chairperson may alter the time specified.
- (c) Consideration of Comments. A proposal published in *PF* for comment shall not be reprinted in *PF* for additional comment prior to publication in the *USP* or the *NF* unless the Expert Committee or the CoE Chairperson determines that reprinting is necessary due to the nature or significance of the comments received or changes made to the proposal. No further opportunity for comment shall be required if changes made to the proposal are in response to comments received and do not create new compendial requirements not contained in the initial *PF* proposal.
- (d) Comment Summary. Where a proposal is published in the *USP* or the *NF* without reprinting in *PF*, such a summary or abstract of each type of comment received and a response to the comment from the Expert Committee or CoE Chairperson shall be posted on USP's website.
- (e) Additional Notice and Comment. In addition to publication in *PF* as provided herein, other means such as the USP website may be used to provide notice of and an opportunity to comment on proposals, if determined appropriate by the Expert Committee, or the CoE Chairperson.

7.07 Approval by Expert Committee

- (a) New Standards and Accelerated Approvals; Conventional Balloting. Prior to publication as final text, all new or revised documentary standards (other than *Errata*) and the suitability of use of any Reference Standard in such documentary standards must be voted on and approved by the responsible Expert Committee. Voting shall be accomplished by ballot. Ballots may be issued or returned electronically, by mail, or any other method. Ballots must be returned by a majority of the members of the Expert Committee by the specified due date for the vote to be valid. Members who are abstaining from voting due to Conflict of Interest or other reasons shall indicate such abstention on their ballots and be counted towards this majority requirement.
- (b) Revised Documentary Standards; Ballot By Consent. A revision of an existing documentary standard not involving the suitability of a Reference Standard may be approved through a consent ballot process whereby the appropriate Expert Committee is informed of the proposed revision and given a reasonable period (at least 5 business days) to request that such revision be reviewed by the Expert Committee prior to being finalized. If two or more Expert Committee members request such a review, the Expert

Committee shall meet and decide whether to: (1) allow the proposal to proceed to finalization unchanged; (2) allow the proposal to be finalized with specific changes, without the need for further Expert Committee action; or (3) require the proposal to be voted on and approved by the Expert Committee through the conventional balloting procedure specified in Section 7.07(a) above. If two or more Expert Committee members do not request such a review within the specified period, the revision may be finalized and approved for release to official status without further Expert Committee action.

- (c) Responsibility for Approvals. When more than one Expert Committee collaborates on a particular proposal, one Expert Committee shall be designated by the CoE Chairperson as the lead Expert Committee and will be responsible for approvals. The other collaborating Expert Committee(s) shall be notified of the approval.

7.08 Postponement

- (a) Request for Postponement. A request for postponement may be filed by anyone and shall be accompanied by a statement of the grounds upon which the postponement is requested and appropriate supporting data. A request for postponement submitted under this section shall be clearly distinguished from a Request for Revision.
- (b) Untimely Requests. A request for postponement received within thirty (30) days prior to the official date may be refused for consideration by the CoE Chairperson if, solely within his or her discretion, he or she considers the request untimely or lacking adequate supporting data. Such decision shall not be subject to appeal, and the matter instead will be considered as a Request for Revision.
- (c) Granting of Postponement. The Expert Committee responsible for approving the standard for which postponement is sought shall have the authority to postpone the official date of any requirement or textual material in such standards; provided that all decisions on postponement requests shall require review and approval by the CoE Chairperson, who may at his or her option refer the matter to the Executive Committee for its consideration. Any postponement shall stay in effect until the responsible Expert Committee considers or approves a subsequent revision to the postponed standard, or the CoE Chairperson or Executive Committee decides to lift the postponement.

7.09 Appeals

- (a) Process. All appeals shall be received and considered as provided in Article VII, Section 6 of the Bylaws and this section.
- (b) Timing of Appeals. A standard may properly be appealed only up to 30 days prior to its official date. Once official or issued, or within 30 days of being official, the matter is not subject to appeal, however, any interested party may request that the matter be considered as a Request for Revision.
- (c) Submission of Appeals. All appeals must be submitted in writing and be accompanied by supporting data and evidence. An appeal submitted under this section shall be clearly distinguished from a Request for Revision. The appellant shall indicate whether an oral hearing is requested or if the appeal should be decided solely based on the submitted documents.
- (d) Determination to Grant or Deny. All appeals of decisions made by an Expert Committee shall be submitted to the CoE Chairperson who, with the consent of the Executive Committee, will make the initial determination whether to grant or deny the appeal. This determination may be based upon whether or not the appeal is accompanied by sufficient data or evidence, is frivolous, or is untimely. The determination to deny an appeal is not subject to appeal; however, any appeal denied will be treated as a Request for Revision.
- (e) Adjudication of Appeals. If an appeal of a decision made by an Expert Committee is granted, the CoE Chairperson shall submit it to the Executive Committee for adjudication. For an appeal via oral hearing, the Executive Committee shall determine the time and

place of the hearing and the CoE Chairperson or his or her designee shall be the presiding officer. The oral hearing may be held by conference call or similar communication by means of which all persons participating in the meeting shall hear one another in the same period of time. The Executive Committee may invite other parties that it deems to have a substantial interest in the matter being appealed to participate in the appeal, including the Expert Committee whose decision is being appealed. At an oral hearing any party may offer such additional evidence deemed necessary to an understanding and determination of the issues. At an oral hearing, witnesses may be called, and a witness presented by one party may be questioned by any other party with regard to the evidence the witness has offered. The Executive Committee shall be the judge of the relevancy and materiality of the evidence offered and conformance to legal rules of evidence shall not be necessary.

- (f) Appeal of Executive Committee Decisions. Where there is an appeal of a decision by the Executive Committee, the appeal will be adjudicated by the Board of Trustees.

8. OTHER DOCUMENTARY STANDARDS

8.01 Food Chemicals Codex

- (a) Requests for Revision. Proposals to create new standards or to revise standards in the *Food Chemicals Codex (FCC)* shall be submitted in accordance with any applicable guidelines developed by USP. The Scientific Liaison shall evaluate the relevancy, supportability, and urgency of the request in accordance with the established policies and procedures and determine whether to proceed with the requested revision. The Scientific Liaison may notify the Food Ingredients Expert Committee (FIEC) of a pending *FCC* request for revision, and may also provide the request to other relevant Expert Committees or Expert Panels.
- (b) Notice and Comment Period. Except as provided in subsections (e) and (f) below, all proposals to revise the *FCC* shall be published in the *FCC Forum* on the USP website for public review and comment. Unless otherwise determined by USP, a proposal that includes the use of a new USP Reference Standard shall not be scheduled for publication in the *FCC Forum* until a suitable reference standard bulk candidate has been received by USP. A period of ninety (90) days from the date of publication in *FCC Forum* will be allowed for public review and comment. For good cause shown, the CoE Chairperson may alter the time specified.
- (c) Approval by Expert Committee and Publication. Following the notice and comment period, the Food Ingredients Expert Committee (“FI EC”) shall review all comments, accept or reject them, and make any final changes to the proposal it deems appropriate. Prior to publication in final form, the proposal must be approved by the FIEC using the voting procedures provided in Section 7.07 above. After approval by the FI EC, the *FCC* proposal shall be published in the next edition of the *FCC* or *Supplement* thereto, as applicable, and shall become effective 90 days from the date of publication unless otherwise provided. Unless otherwise determined by USP, a revision to the *FCC* that includes the use of a new USP Reference Standard shall not be published as final approved text until the required USP Reference Standard is available.
- (d) Expedited Standards. If the FI EC determines that for public health or other appropriate reasons, a new or revised standard should be made available prior to publication of the next edition of the *FCC* or *Supplement*, it may be posted as final on the USP website following notice and comment under subsection (b) and approval by the FIEC under subsection (c). Such a standard (“Expedited Standard”) will be effective upon website publication, unless a delayed effective date is specified therein. Upon publication of the next edition of the *FCC* or *Supplement* thereto, as applicable, any Expedited Standard that has become effective since publication of the last edition or *Supplement* will be included in such volume and removed from the USP website.

- (e) Immediate Standards. In those rare cases where the FI EC determines that a new or revised standard should be made available immediately because of an urgent public health need, a standard may be approved by the FI EC and posted as final on the USP website without the notice and comment period specified in subsection (b) above. Such a standard ("Immediate Standard") will be effective upon website publication, unless a delayed effective date is specified therein. Upon publication of the next edition of the *FCC* or *Supplement* thereto, as applicable, any Immediate Standard that has become effective since the last edition or *Supplement* will be included in such volume and removed from the USP website.
- (f) Errata. Errata are considered to be text erroneously published in the *FCC* or its *Supplements* that do not accurately reflect the intended requirements as approved by the FI EC. A list of errata and corresponding corrections to an edition of the *FCC* or to a *Supplement* shall be published on USP's website, until the publication of the next edition of the *FCC* or *Supplement*, which shall then reflect such corrections. Errata shall not be subject to notice and comment and shall not require approval by the FI EC.

8.02 Non-U.S. Monographs; Standards for Articles Legally Marketed Outside the U.S.

- (a) Requests for Revision. Proposals to create new monographs or to revise monographs for articles legally marketed outside of the U.S. (Non-U.S. Monograph) shall be developed in accordance with the USP Non-US Monographs Guideline, available on USP's website.
- (b) Approval by Expert Committee. Following the notice and comment process outlined in the Guideline, the Non-U.S. Monograph proposal must be approved by the relevant Expert Committee using the voting procedures provided in Section 7.07(a) above.
- (c) Publication. After approval by the relevant Expert Committee, a Non-U.S. Monograph proposal shall be published and maintained on the USP website as a final Non-U.S. monograph and shall be considered authorized text. Any subsequent comments received shall be treated as proposed revisions of a Non-U.S. monograph in accordance with subsections (a) and (b) above.

8.03 Pending Monographs

- (a) Request for Revision. Proposals to create new monographs for articles pending FDA approval shall be submitted in accordance with the USP Pending Monographs Guideline, available on USP's website.
- (b) Approval by Expert Committee. Following the notice and comment process outlined in the Guideline, the Pending Monograph proposal must be approved by the relevant Expert Committee using the voting procedures provided in Section 7.07(a) above.
- (c) Publication. After approval by the relevant Expert Committee, a Pending Monograph shall be published and maintained on the USP website as a final Pending Monograph and shall be considered authorized text. Any subsequent comments received shall be treated as proposed revisions of a Pending Monograph in accordance with subsections (a) and (b) above. After FDA approves the article to be marketed in the U.S., the standard will become official and be moved to *USP-NF* by Revision Bulletin if approved by the relevant Expert Committee, as provided in the Pending Standards Guideline.

8.04 Medicare Model Guidelines

The Council of Experts shall be responsible for developing and approving revisions to the Model Guidelines and related information and documents that pertain to formularies and plan designs that may be used by prescription drug plans under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. The Executive Committee of the Council of Experts shall create a Guideline to outline the processes and procedures for this activity, shall make such Guideline available on USP's website, and shall appoint a Model Guidelines Expert Panel to execute this work.

9. Advisory Stakeholder Forums and Project Teams

9.01 Formation

Stakeholder Forums and Project Teams may be formed by the CoE Chairperson.

9.02 General

- (a) Membership. Stakeholder Forum and Project Team members shall serve as representatives of an organization, company, or service provider. Members of the Board of Trustees, Council of Experts, and Expert Committees may participate in Stakeholder Forum and Project Team discussions, but only as representatives of USP.
- (b) Advisory Nature. Stakeholder Forum and Project Team deliberations are advisory and are not binding in any way on the Council of Experts, its Expert Committees, or USP staff.
- (c) Travel Expenses. When attending a meeting, Stakeholder Forum and Project Team members' travel and accommodation arrangements and costs are the responsibility of the individual Stakeholder Forum or Project Team member, unless otherwise indicated by USP.

9.03 Stakeholder Forums

- (a) Purpose. Stakeholder Forums shall be formed to enable an exchange of information and perspectives, with the ultimate goal of improving USP standards and information. Stakeholder Forums may exist in any region in which USP operates and may focus on any general compendial offering.
- (b) Formation. The decision to form a Stakeholder Forum will be made by the CoE Chairperson. When establishing a Stakeholder Forum, the CoE Chairperson shall develop a specific charge for the Stakeholder Forum, including goals and expected outcomes. Multiple Stakeholder Forums can be formed and will continue until dissolved by the CoE Chairperson.
- (c) Membership. Membership of Stakeholder Forums will consist of organization, company, and service provider representatives that may be affected by USP actions and who, in turn, might affect USP activities. Each representative organization may appoint up to three representatives to attend a Stakeholder Forum meeting; provided, however, that the CoE Chairperson shall have the right to limit or adjust the number of attendees from each organization to ensure balanced representation across constituencies. Membership may also include other individuals that the CoE Chairperson determines may provide useful insight or perspective on USP activities or the underlying science. The CoE Chairperson shall determine the organizations, companies, service providers and individuals that may be a member of a particular Stakeholder Forum.
- (d) Chair. Stakeholder Forum members, with the advice and consent of the CoE Chairperson, will select the chairperson(s) of such Stakeholder Forum. Subsequent rotation of chairperson(s) of a Stakeholder Forum is at the Stakeholder Forum's discretion. The chairperson(s) of a Stakeholder Forum leadership shall work with USP staff to create agendas for each meeting. The Stakeholder Forum may elect to create a planning committee to manage that activity. The chairperson(s) will preside over the Stakeholder Forum meetings.
- (e) Meetings. Stakeholder Forum meetings may be held as face-to-face meetings at USP Headquarters or other locations, or via Web meeting. Dates and times will be posted on the USP website and are open to attendance by other interested individuals who may attend as observers.
- (f) Reports. A final summary report of a Stakeholder Forum will be prepared at the close of the cycle by the Stakeholder Forum and USP.

9.04 Project Teams

- (a) Purpose. Project Teams generally shall be formed to address a specific compendial topic (primarily process-oriented). Project Teams will function under a particular Stakeholder Forum.
- (b) Formation. The formation of a Project Team may be initiated by the CoE Chairperson. Members of a Stakeholder Forum may recommend formation of a Project Team to the CoE Chairperson. When forming a Project Team, the CoE Chairperson shall develop a specific charge for the Project Team, including goals and expected outcomes, with input from the related Stakeholder Forum. Project Teams will continue until completion of their charge or until dissolved by the Chairperson.
- (c) Membership. Members of Project Teams shall be appointed by the CoE Chairperson, based on recommendations from the related Stakeholder Forum and/or on their scientific or technical expertise. The CoE Chairperson shall determine the appropriate number and type of representatives on the Project Team, with input from the Stakeholder Forum.
- (d) Chair. Each Project Team, with consent of the CoE Chairperson, shall select a Project Team chairperson. Subsequent rotation of chairpersons of a Project Team is at the Project Team's discretion. The chairperson shall preside over the Project Team's meeting(s) and will interact with USP staff on behalf of the Project Team.
- (e) Meetings. Upon formation of a Project Team, an initial kick-off meeting shall be held with the Project Team and appropriate USP staff and Council of Experts or Expert Committee members. Subsequent meetings of the Project Team will occur as determined necessary by the Project Team, and may be face-to-face, via teleconference, or via Web meeting. USP staff shall attend such subsequent meetings as requested by the Project Team.
- (f) Reports. Project Teams shall report progress to the appropriate Stakeholder Forum. The Project Team shall provide periodic reports as requested by USP staff and on completing its charge, shall prepare a final report with conclusions and recommendations. USP staff will respond to the issues, in writing, as appropriate and necessary.

10. MEETINGS

10.01 Expert Committee and Expert Panel Meetings

- (a) Open Meetings. In accordance with USP's Open Meeting Policy, a meeting of an Expert Committee or Expert Panel shall be open to the public, except that a meeting or a portion of a meeting may be closed if the chairperson of the Expert Committee or Expert Panel or the CoE Chairperson determines that there is good and sufficient reason for closure. Such reasons may include, and are not limited to: review or discussion of trade secret or confidential, commercial information; or review or discussion of matters the premature disclosure of which could be detrimental to the USP.
- (b) Closed Meetings. If the determination is made to close a meeting, such determination and the reason for closure shall be announced at the beginning of the meeting and noted in the meeting minutes. Any non-member participants attending such meeting (other than FDA or other Government Liaisons, as described in 10.04(b) below) shall be excused from the meeting.
- (c) Teleconferences. An Expert Committee or Expert Panel may hold a meeting by means of a teleconference, Web meeting, or other communications mechanism by which all persons participating in the meeting can hear one another or perceive each other's comments. Participation by such means shall constitute presence in person at a meeting. A meeting held by means of a teleconference, Web meeting, or other

communications mechanism shall provide an opportunity for public participation unless the meeting is closed as provided above.

10.02 Council of Experts and Executive Committee Meetings

Meetings of the Council of Experts and Executive Committee shall be closed unless otherwise indicated.

10.03 Announcement of Public Meetings and Minutes

To the extent possible, all USP open meetings shall be announced beforehand by appropriate means, which shall include the USP Web site. Minutes of Expert Committee and Expert Panel meetings shall be available by requesting them from the USP Executive Secretariat, excluding minutes from any closed portion thereof.

10.04 Non-member Participants in Expert Committee or Expert Panel Meetings

When a USP meeting is open to the public, a non-member may participate in one of three ways:

- (a) Invited Guest. Invited guests are non-members who are invited specifically to share a particular expertise or express their particular point of view. This shall be carried out under the control of the chairperson of the Expert Committee or Expert Panel and shall be subject to the Rules and Procedures of the Council of Experts. These non-members shall be provided with appropriate briefing materials, excluding confidential information. The Expert Committee or Expert Panel chairperson shall ask the invited guest to be excused during a confidential discussion or deliberation.
- (b) Government Liaisons. Government Liaisons are representatives from the Food and Drug Administration or other governmental agencies in the U.S. or other countries who desire to participate in an Expert Committee or Expert Panel in their capacity as government employees. Government Liaisons generally shall receive briefing materials and be allowed to participate in confidential discussions occurring at a meeting, provided that they have signed confidentiality agreements for such meeting requiring them to keep all such information confidential except to the extent limited disclosure within the respective agency is required in the performance of their governmental duties. The Expert Committee or Expert Panel chairperson may ask a Government Liaison to excuse himself or herself during any discussion or deliberation in which the chairperson believes such Government Liaison's participation would not be appropriate due to confidentiality, conflict or other reasons.
- (c) Observers. Observers, including press and representatives of government agencies not officially designated as Government Liaisons, are non-members who themselves choose to attend the Expert Committee or Expert Panel meeting. Observers must notify USP **at least five business days** in advance of the meeting (or as soon as possible after posting of the meeting notice and agenda) of their proposed attendance, and provide necessary background information about themselves. Observers may or may not receive briefing materials. USP retains the right to refuse permission for an observer to attend a meeting. The Expert Committee or Expert Panel chairperson shall ask the observer to excuse himself or herself during a confidential discussion or deliberation. Observers will be permitted to make presentations or otherwise speak at the meeting only if approved in advance by the chair of the Expert Committee or Expert Panel.

10.05 Working Sessions and Status Conferences

Two or more members of an Expert Committee or Expert Panel may engage in informal dialogue and working sessions as part of their work, and an Expert Committee or Expert panel may hold informal teleconferences and online discussions to review the status of work being performed by members, without the need to call or conduct a formal meeting of the Expert Committee or Expert Panel as provided herein. Except as provided in Section 7.07 above, any decision on any substantive issue shall be made by an Expert Committee or Expert Panel only at a meeting called and conducted in accordance with the provisions of Sections 10.01 through 10.04 above.