Standards-Setting Activities

"At USP, we are committed to ensuring that our standards are based on accurate, reliable scientific data and other supporting information."

USP is a global leader in public standards-setting to help ensure the quality, safety, and benefit of medicines and foods. To maintain our excellence as a standards-setting organization, USP will establish standards and information through processes that are open, rigorous, science-based, and unbiased. USP will design, implement, and maintain quality management systems to continuously monitor, improve, and measure the quality and impact of USP products and services. USP will hold open meetings and publish standards impartially. USP will not provide information about our standards, or standards-setting activities, in a manner that will allow any stakeholder to have an undue advantage over another stakeholder.

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Scientific Integrity

At USP, we are committed to ensuring that our standards are based on accurate, reliable scientific data and other supporting information, to help ensure the medicines used are of needed and expected quality. The currency of our standards are maintained through a continuous revision process reflective of the technological changes in manufacturing and testing procedures. All employees and volunteers who contribute to our standards-setting activities must rigorously evaluate scientific data and any other input to decision

making, honestly report results of their analysis, and adhere to SOPs for preserving the quality of USP standards. Any employee found to have intentionally submitted false or misleading information in support of a USP standards-setting activity will be subject to appropriate disciplinary measures, up to and including termination.

Quality Management Systems

At USP, we operate under a rigorous quality management system. As USP employees, we are all responsible and accountable for reading, understanding, and complying with the *USP Corporate Quality Manual* and all standard operating procedures applicable to our specific functions. Everyone is responsible for the quality of the work they produce. Everyone is expected to be familiar with the Quality Policy and understand how their jobs relate to it.

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Official Statements and Interpretations

USP text and publications may have legal implications in the United States and elsewhere; therefore, their language must stand on its own. As USP employees, volunteers, and representatives, we may not provide an official after-the-fact interpretation to one party, thereby placing other parties who have not received that interpretation at a possible disadvantage.

In addition, we may not provide an official opinion as to whether a particular article does or does not comply with compendial requirements, except as part of an established USP verification or other conformity assessment program that is conducted separately from, and independent of, USP's standards-setting activities.

Document Disclosure

USP provides disclosure of information and records regarding USP standards-setting activities consistent with:

- The rights of individuals to privacy
- USP's need to protect the confidentiality of trade secrets and other proprietary commercial or financial information
- USP's need to promote frank internal deliberations and to pursue standards-setting activities without disruption

Pursuant to this policy, general information pertaining to standards-setting and other activities, including information regarding the work and deliberations of USP's Council of Experts and Expert Committees, is posted and maintained on the USP website.

In addition, communications between USP and third parties relating to standards-setting activities will be made available upon specific written request, including copies of written correspondence to and from third parties and memoranda of telephone conversations and meetings with third parties. Such third-party communications do not include communications of any kind among or between USP staff and members of the Board of Trustees, Council of Experts, or Expert Committees. Furthermore, unless required by law, USP will not disclose documents containing any trade secrets or confidential commercial secrets of third parties, if the confidentiality was specifically stated when the documents were submitted to USP. However, documents submitted to USP by a third party containing trade secrets or confidential commercial secrets that ordinarily would be contained in a New Drug Application or Supplement thereto may be disclosed to the U.S. Food and Drug Administration upon its request in its review of any revision or proposed revision of the *United States Pharmacopeia, National Formulary*, or other USP compendium.

All requests for documents shall be made to the USP Executive Secretariat, which shall be responsible for decisions about disclosure of information. A request may be refused solely on the basis that it is unduly burdensome or if USP determines that diversion of personnel from higher-priority duties would be unreasonable.

USP reserves the right to charge reasonable fees for disclosure of any documents requested under this policy, including photocopying charges; charges for time spent by USP personnel to locate, review, and copy such documents; postage fees; and other expenses associated with responding to the request.

Public Participation in Open Meetings

All meetings of USP Expert Committees shall be open to the public, except that a meeting or a portion of a meeting may be held in closed session if the Chairperson of the Expert Committee or the Chairperson of the Council of Experts determines in his or her discretion that there is good and sufficient reason for closure. Such reasons may include review or discussion of trade secrets or confidential, commercial information or review or discussion of matters whose premature disclosure could be detrimental to USP's standards-setting activities. If a determination is made to close a meeting, then the reason for such closure shall be noted in the minutes of the meeting. Attendance at a meeting of an Expert Committee shall be subject to the provisions set forth in the *Rules and Procedures of the Council of Experts* and the procedures posted on USP's website. A public calendar shall be maintained and posted on the USP website showing, to the extent feasible, future Expert Committee meetings.

Audio and video recordings may be made at any open meeting or conference if approved in advance by USP so as to avoid disruption of the proceedings. The Chairperson of the Expert Committee or the Chairperson of the Council of Experts may decline permission for audio or video coverage that would adversely affect the meeting.