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January 7, 2018

Convention Governance Committee (CGC)  
United States Pharmacopeia  
2601 Twinbrook Pkwy,  
Rockville, MD 20852

Reference: Notice of Proposed Change to 2015-2020 Rules and Procedures of the Council of Experts

Dear CGC Members:

PDA appreciates the opportunity to respond to the proposed change to section 7.06 of the Rules and Procedures of the 2015-2020 Council of Experts, Approval by Expert Committee. PDA and its members appreciate the challenges of a growing workload with limited resources faced by the Expert Committees under the current rules and procedures. PDA can support the delegation of certain specific Expert Committee tasks to appropriately trained and qualified USP staff as long as there is no scientific impact or risk to patients or public health. PDA would like to see the revision include more precise language on what can or cannot be delegated. For example, PDA recommends the procedure state that changes to standards, test methods or specifications for items other than editorial or format or error corrections will not be delegated. PDA agrees with the delegation to USP staff of changes due to typographical errors or editorial errors that do not change science such as already done with reference standards.

One concern PDA has with this proposal is that it creates new numbering for the various parts of section 7.06 as shown in the table below.



Structure of Current Section 7.06	Structure of USP Proposed Section 7.06
(a) New Standards and Accelerated Approvals; Balloting	(a) New Standards and Accelerated Approvals; Balloting
(b) Joint Standard-Setting Subcommittee; Approval; Balloting	(b) USP Staff; Delegation of Approval Authority with Council Oversight
(c) Responsibility for Approvals	(c) Joint Standard-Setting Subcommittee; Approval; Balloting

There are multiple issues here. First, the original section 7.06c appears to be missing in the proposal. It is unclear whether this part being deleted. Second, the renumbering of the parts (e.g., old b is new c) is problematic because other documents (e.g., Guideline for Review and Approval of Reference Standards...) directly reference these parts. The renumbering will create errors in these other documents and lead to confusion. PDA recommends the old numbering remain intact and a new sub-bullet (d) for USP Staff Delegation be created as shown below.

Structure of PDA Proposed Section 7.06
(a) New Standards and Accelerated Approvals; Balloting
(b) Joint Standard-Setting Subcommittee; Approval; Balloting
(c) Responsibility for Approvals
(d) USP Staff Delegation of Approval Authority with Council Oversight

PDA would also like to suggest alternate ways to address the constraints the ECs are facing. One approach is to split Expert Committees within the larger or more busy topics so that that workload could be divided without overlap. Advantages of this approach include involvement of more volunteers from industry bringing broader perspectives and expertise to the discussions and lowering the burden on each individual expert committee member. One challenge could be the additional considerations for the USP staff to manage and support an increased size of the Council of Experts. This approach of sub dividing current expert committees develops more experience within the volunteer base and provides increased opportunities for succession planning for expert committee leaders. One example would be the Chemical Analysis committee where the scope could be split into two groups such as spectroscopy and chromatography.

PDA is a non-profit international professional association of more than 10,000 individual member scientists having an interest in the fields of pharmaceutical, biological, and device manufacturing and quality. Our comments were prepared by a committee of experts with experience in pharmaceutical manufacturing and pharmacopeia publications including members representing our Board of Directors and our Regulatory Affairs and Quality Advisory Board.

If there are any questions, please do not hesitate to contact me.

Sincerely,

Richard Johnson  
 President, PDA  
 Cc: USP Board of Trustees