Recent Modifications to the USP Standards-Setting Process

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At the March 29, 2006 Spring Governance Meeting, the 2005–2010 USP Council of Experts voted to approve changes to the Rules and Procedures of the 2005-2010 Council of Experts, which were originally adopted on a provisional basis in April 2005. Pursuant to USP's Bylaws, the revised Rules and Procedures were made available to USP's Convention membership for comment, reviewed and approved by USP's Board of Trustees, and formally adopted by the Council of Experts.

Further details on the changes to the Rules and Procedures will be posted here soon. Meanwhile, the following is a summary of the changes:

- A strengthened ability for Expert Committees to make final decisions on standards without multiple resubmissions to PF.
- An increased responsibility by USP to respond to public comments, both to the commenter and in the *USP-NF* or Supplement.
- The ability for increased use of the USP website for the standards-setting process.
- Provisions for Information Expert Committees, which were previously omitted due to the delay in electing Information Expert Committee chairs and members.
- Provisions for several new USP initiatives, including Standards for Articles Legally Marketed Outside the U.S. and USP-NF translations.
- Provisions to enable a third classification of observers, FDA Observers, to participate in USP Expert Committee meetings.
- Miscellaneous clarifications/corrections.

Please direct any comments or questions on this topic to Susan de Mars, Chief Legal Officer (+1-301-816-8296 or sdm@usp.org).