

FOR IMMEDIATE RELEASE

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## Quality Standards for Widely Used Medicines Strengthened

### USP Teaming with FDA and CHPA to Apply Modern Test Methods to Acetaminophen, Other Common Medications

Rockville, Md., March 21, 2011 — As part of its ongoing mission to protect public health, the U.S. Pharmacopeial Convention (USP) is working with the Food and Drug Administration (FDA) and the Consumer Healthcare Products Association (CHPA) to update quality standards for widely used medicines and ingredients. Several years ago, USP put in place an ambitious, long-term effort to assess written (or documentary) standards for prescription and over-the-counter (OTC) drugs published in the United States Pharmacopeia and National Formulary (USP–NF) compendia, aimed at stepping up the pace of revising test procedures where needed to reflect scientific advances. Coupled with this is USP's ongoing commitment to make available official USP Reference Standards (physical samples) for procedures described in documentary standards. The working relationships with FDA and CHPA fit into that overall initiative, focusing on an initial list of priority medicines and ingredients identified by FDA. The USP–NF provides specifications for the identity, as well as quality, purity and strength of drugs and their ingredients, which are enforceable by FDA in the United States. USP standards are used in more than 130 countries.

FDA Commissioner Margaret Hamburg, M.D., expressed support for USP's standards modernization project during her remarks at the USP Convention meeting in April of 2010, citing this effort as one of the most pressing tasks facing both USP and FDA given documented incidents of poor-quality prescription and OTC products. Updated test methodologies are crucial to help counter economically motivated adulteration (in which less expensive and potentially harmful ingredients are substituted for genuine medicines or their ingredients), and also to address the challenge of impurities that may go undetected with older, non-specific assays and tests.

"FDA and USP have a long-standing partnership in law that helps ensure the quality of the American drug supply," said Roger L. Williams, M.D., USP's chief executive officer. "In the current effort, we are pleased to be joined by CHPA as well, as this initiative would not be possible without the active participation of industry. FDA has identified a number of medications and ingredients commonly used in prescription and OTC products

that may be vulnerable to economically motivated adulteration or are associated with other concerns, which has helped focus our efforts. USP is working to make sure the quality standards for these products are based on the best current analytical procedures and allied reference materials to resolve such concerns. American patients, consumers and practitioners have a right to expect this.”

In addition to the first list of products and ingredients for USP's priority attention, FDA will continue to recommend candidate standards for updating. An example of an FDA recommendation is a test for impurities and degradants in products containing acetaminophen—one of the highest-volume OTC drugs and one that is also used in many prescription medications. Other commonly used ingredients to be updated include dextromethorphan (a cough suppressant) and diphenhydramine (an antihistamine).

USP will consider all recommendations for updates through its well-established process, in which volunteer experts evaluate standards, solicit commentary from the stakeholder community and ultimately decide on changes to incorporate. USP invites and encourages all stakeholders to provide input into the modernization initiative, and is seeking comment from manufacturers of products and ingredients included in the priority list of standards to be updated—as well as from the practitioner and consumer advocate communities. FDA's priority list and background information on the standards modernization initiative may be found at [www.usp.org/hottopics/monographs.html](http://www.usp.org/hottopics/monographs.html). Also on this Web page, USP has issued a call for volunteer experts for the Acetaminophen Monograph Expert Panel, which will provide recommendations for revisions to the Expert Committee.

For more information, please contact [mediarelations@usp.org](mailto:mediarelations@usp.org).

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The United States Pharmacopeial Convention (USP) is a scientific, nonprofit, standards-setting organization that advances public health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods. USP's standards are relied upon and used worldwide. For more information about USP visit <http://www.usp.org>.