



U.S. Pharmacopeia
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New Tests for Identifying Harmful and Potentially Deadly Adulterants in Pharmaceutical Ingredients Part of Revised Standards

Revisions Will Apply to Four Common Pharmaceutical Excipients, Will Be Legally Enforceable for U.S.-Marketed Products

Rockville, Md., October 30, 2009 — To further protect patients from adulterated medicines, the U.S. Pharmacopeial Convention (USP) today announced revised standards for four ingredients widely used in prescription and over-the-counter drugs. The standards, posted on the USP Web site, include new tests for identifying two harmful and potentially deadly contaminants in the four pharmaceutical excipients—inactive ingredients common in medicines for purposes including sweetening agents and solvents.

USP is a nonprofit, scientific organization that sets legally recognized standards designating the identity, quality, purity, strength and consistency of prescription and over-the-counter medications and their ingredients in the United States. These standards are enforced by the U.S. Food and Drug Administration (FDA). The revisions respond to a request from FDA to revise the USP Propylene Glycol and Sorbitol Solution standards to include limits for diethylene glycol (DEG) to help prevent future episodes of pharmaceutical adulterations with this poisonous chemical. DEG is commonly used in antifreeze and has no legitimate place in medicines. Adulterations of cough syrups and other products with DEG have occurred many times and in many countries, including a tragic episode between November 2008 and January 2009 in which 84 children in Nigeria died after ingesting teething syrup contaminated with DEG. A similar episode occurred in July 2009 in Bangladesh, killing at least 24 children.

The revisions come after USP recently updated its standard for Glycerin, another pharmaceutical excipient. Consistent with the Glycerin revision, the updated “high priority” standards for the pharmaceutical excipients will help ensure the absence of DEG and ethylene glycol (EG), another poisonous chemical, each at a level of not more than 0.10 percent. The standards will become official February 1, 2010, allowing for a 12-week implementation period. All manufacturers using these pharmaceutical excipients in their U.S.-marketed products will be required to comply with these new standards once official.

“The adulteration of drugs and their ingredients is a critical public health issue,” said Susan de Mars, USP chief documentary standards officer. “As recently as a few months ago, this was tragically illustrated in separate instances in Bangladesh and Nigeria. USP, in close collaboration with FDA, manufacturers, and other national and international parties, is addressing this by updating our standards for ‘at risk’ products. The unfortunate reality of economic incentives to counterfeit medicines makes this necessary.”

The revision effort additionally proposed new standards for USP Sorbitol Sorbitan Solution and Noncrystallizing Sorbitol Solution. The four revised monograph standards were originally posted on the USP Web site on July 1 to allow

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manufacturers, regulators and all other interested parties until August 14 to review the proposed changes—found in the “Identification” sections of the monographs—and provide informal comment on USP’s approach prior to its formal posting via USP’s Revision Bulletin process. USP also held three open Web meetings to communicate these proposed revisions to stakeholders.

In addition to the written standards, USP has developed physical reference materials for the pharmaceutical excipients as well as impurities reference materials for DEG and EG. These physical materials are used by manufacturers and regulators to ensure a substance meets the USP written standards.

For more information, visit

www.usp.org/hottopics/propyleneGlycolSorbitolInformation.html or email mediarelations@usp.org.

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USP—Advancing Public Health Since 1820

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 recognized and used worldwide. For more information about USP visit <http://www.usp.org>. **FY1016**