



U.S. Pharmacopeia
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USP Announces New Standards to Protect Patients from Counterfeit and Adulterated Medicines

Will Help Keep Dangerous Ingredients Out of the U.S. Market and Better Secure the Nation's Drug Supply

Rockville, Md., February 4, 2009 — With counterfeit and adulterated medicines posing an increasing risk to patients in the United States and worldwide, the U.S. Pharmacopeial (USP) Convention today announces new standards for two widely used drug products that have been involved in episodes of adulteration resulting in patient deaths.

The release of these standards, for the blood thinner heparin and the sweetener glycerin, comes on the heels of recent and dangerous incidents involving the two products. More than 200 patients worldwide reportedly died after batches of heparin were adulterated with over-sulfated chondroitin sulfate—which can be derived from the dietary supplement chondroitin and can mimic heparin's blood-thinning properties. Glycerin, used in many drugs and consumer goods such as cough syrups and toothpaste, has been involved in numerous episodes in which diethylene glycol, a poisonous chemical used in antifreeze, was added either intentionally or accidentally as a lower-cost substitute for glycerin, most recently in Nigeria in 2008.

“The tragedies involving heparin and glycerin demonstrate the shortcomings of 20th century safety nets in a 21st century global manufacturing supply chain,” noted Roger L. Williams, M.D., USP's chief executive officer. “The reality is that with the decentralized, complex and global nature of today's manufacturing environment, it is too easy for an unscrupulous supplier—driven by economic or even more frightening motives—to add an ingredient to a drug product that shouldn't be there, putting us all at risk. These suppliers are increasingly sophisticated in their methods, resulting in a very dangerous situation. Rigorous quality standards such as the ones announced today form a line of defense that helps to protect the public.”

“These new USP quality standards provide better assurance of the quality of marketed products by using appropriate and modern analytical methods,” says Moheb Nasr, Ph.D., director, Office of New Drug Quality Assessment (ONDQA), CDER, FDA. “This provides a considerable safeguard for citizens of the United States and the world by helping to prevent fraudulent suppliers from adding components that in the past have eluded existing identity tests due to similar properties. The new standards represent a significant improvement to the safety nets that keep substandard drugs from reaching the marketplace. FDA is pleased to have worked together with USP on this effort.”

All manufacturers whose products are used in the United States must comply with these new standards, which are scheduled to become official in May 2009 for glycerin and August 2009 for heparin (after a public comment period), and are enforceable by FDA. More information on the new heparin standards can be found

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here: <http://www.usp.org/pdf/EN/aboutUSP/heparinStatement.pdf> and the new glycerin standard can be found here: <http://www.usp.org/pdf/EN/aboutUSP/glycerinStatement.pdf>.

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USP—Advancing Public Health Since 1820

The United States Pharmacopeial (USP) Convention is a private, non-profit, 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/newscenter>. **FY0929**