



U.S. Pharmacopeia
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USP Proposes New Standards for Heparin to Protect Patients in Response to Recent Adulteration

Rockville, Md., February 4, 2009 — As part of its ongoing effort to protect the quality and purity of the widely used blood-thinner heparin, the U.S. Pharmacopeial (USP) Convention today announces it has completed a second round of revisions to its heparin standards that includes state-of-the-art tests to detect potential contaminants. These monograph, or written, standards for heparin sodium and heparin sodium injection are now available for public review and comment. USP initially undertook the revisions at the request of the U.S. Food and Drug Administration (FDA) in response to the recent episode of adulteration of the drug that resulted in the reported deaths of more than 200 patients worldwide.

This is the second stage of a two-stage process to update USP's heparin monograph standards after it was recently discovered that many batches of the drug were adulterated with over-sulfated chondroitin sulfate. This adulterant can be derived from the dietary supplement chondroitin and can mimic heparin's blood thinning properties in a chemically induced over-sulfated form, allowing it to pass previous quality tests. Such tests are normally designed to look for known impurities resulting from the manufacturing process or degradation rather than unknown contaminants that may be added deliberately—as was the case with heparin.

To better secure the immediate supply of the drug for doctors and patients and to address the public health crisis at hand, USP released a first revision to its heparin monograph standards in June 2008 that included new identity tests to detect over-sulfated chondroitin sulfate. This expedited revision was followed by a thorough modernization of the monograph standards that now includes current methods and technology that are broadly usable by manufacturers.

“The existence of good public standards is crucial in guarding against adulterated and substandard medicines,” said Roger L. Williams, M.D., USP's chief executive officer. “USP's work with our independent scientific experts, FDA and other pharmacopeias of the world in developing these revised heparin standards updates protections for the quality of this important drug in the United States and in countries around the world that follow USP's standards.”

The proposed new monograph standards are available on USP's Web site at www.usp.org in advance of publication in *Pharmacopeial Forum (PF)*. *PF* is the journal through which USP accepts public comment on proposed standards to be included in the *United States Pharmacopeia–National Formulary (USP–NF)* compendia. USP will be soliciting further feedback on its proposed changes through an open Web meeting to be held in late February 2009. The public comment period ends May 15, 2009. After gathering feedback, the Blood & Blood Products Expert Committee of the USP Council of Experts, USP's scientific decision-making body, will decide on the final standards. These will become official in August 2009. Official USP Reference Standards—the vials of chemicals that manufacturers use in testing to ensure that their pharmaceutical substances are meeting the USP monograph standards for quality, purity and strength—also will be available at that time.

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After the standards are official, all manufacturers who market heparin sodium and heparin sodium injection in the United States will be required to meet these new standards, as described in the Federal Food, Drug, and Cosmetic Act—which designates *USP–NF* compendial standards (including monographs, General Chapters, and related reference standards) as the country’s official standards for quality, purity, strength and consistency. These standards are enforced by FDA.

For more information on specific changes to the monograph standards or on the upcoming Web conference, visit www.usp.org or contact mediarelations@usp.org.

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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>. **FY0927**