



U.S. Pharmacopeia
The Standard of Quality™

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Supply of Blood Thinner Heparin Further Secured

USP Releases Second Stage of Quality Standards Revisions

Rockville, Md., October 1, 2009 — Further helping to secure public health, a second round of revised quality standards for the widely used blood thinner heparin became effective today, the U.S. Pharmacopeial (USP) Convention announced. Working closely with the Food and Drug Administration (FDA), the pharmaceutical industry, and other regulatory and scientific bodies, USP started initial revisions in 2008 after adverse reactions and deaths resulted from heparin intentionally adulterated with over-sulfated chondroitin sulfate (OSCS). OSCS is a less costly substance that can mimic the blood-thinning properties of heparin. The immediate public health crisis was addressed by the first stage of quality revisions released by USP in June of 2008, but a thorough modernization of the existing heparin monographs was needed to ensure the continuing quality of heparin. Those second stage tests and accompanying reference materials that enable manufacturers to compare their products to a proven standard were first announced by USP in February of 2009. Following a period of public comment, the standards are now enforceable in the United States by FDA.

“It has been gratifying to see so many dedicated scientists and regulators collaborating successfully and in an expedited manner in the interest of protecting patients,” said Roger L. Williams, M.D., chief executive officer of USP. “The growth of economically motivated adulteration of medicines worldwide is a tragic by-product of global supply chains, and the safety nets that protect us all must be constantly re-assessed and improved. The second stage of heparin standards revisions represents a significant step forward in strengthening those safety nets, and I look forward to ongoing collaborations to enhance them still more.”

As part of the second-stage revisions, USP has harmonized dosage measurement units with those established by the World Health Organization (WHO). This harmonization means a more uniform worldwide standard. To give manufacturers and practitioners the opportunity to fully understand the revisions, FDA and industry will conduct communications outreach to clinicians and hospitals. USP and FDA are now starting work on a third stage of revisions to the heparin standards, which will involve laboratory research designed to bring even greater sensitivity and precision to the tests and standards used to help ensure drug quality.

For more information, visit www.fda.gov or www.usp.org/hottopics/heparin.html; or email mediarelations@usp.org.

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USP—Advancing Public Health Since 1820

The United States Pharmacopeial (USP) Convention 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>. **FY1010**

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