FOR IMMEDIATE RELEASE

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USP Announces Change in Labeling Requirement for Total Strength of Heparin to Help Minimize Medication Errors

Revised Standard for Heparin Sodium Injections, Lock Flush Solutions Will Clarify Expression of Dose

Rockville, Md., November 5, 2012 — To address safety concerns about the expression of drug strength on labels for heparin sodium injections and heparin lock flush solutions, the U.S. Pharmacopeial Convention (USP) has revised its current standards for these products. Heparin is a widely used anti-coagulant agent, or blood thinner. Medication errors related to misunderstanding of the expression of total strength on multi-dose product labels have the potential to result in serious consequences to patients. The revised standards will become official on May 1, 2013.

USP is a scientific not-for-profit organization that develops standards for the identity, strength, quality and purity of drugs and drug ingredients marketed in the U.S. Published in USP's official compendia, *United States Pharmacopeia* and the *National Formulary (USP–NF),* USP's written, or documentary, standards come in two forms—monographs and general chapters. Monographs provide specifications for individual drug products or substances. General chapters include procedures and methods that apply across a number of monographs. Both monographs and general chapters may also include requirements related to packaging, storage and labeling.

The labeling sections of the currently official Heparin Sodium Injection and Heparin Lock Flush Solution monographs in *USP–NF* are being revised to ensure that labels comply with General Chapter <1> *Injections*. General Chapter <1> requires that the label reflect strength per total volume as the primary expression of strength followed in close proximity by strength per milliliter (mL). An example of an expression of product strength as articulated in General Chapter <1> would be "30,000 USP Units/30 mL (1000 USP Units/mL)."

In a July 2010 letter from the U.S. Food and Drug Administration (FDA) to USP, the agency referred to data indicating that containers labeled only with product strength statements written as "mg per mL" are often misunderstood by healthcare practitioners as total drug content statements. Such errors could result in improper dosing with serious outcomes, including death. FDA's concerns were evaluated by USP's Safe Medication Use Expert Committee (now part of USP's Nomenclature, Safety, and Labeling Expert Committee), composed of 18 experts—many of whom are specialists in patient safety—representing multiple health professions including medicine, nursing and pharmacy. The FDA was also represented by liaisons to USP's Expert Committee.

"USP is committed to developing standards that help to advance public health, " said Roger L. Williams, M.D., USP's chief executive officer. "It is our goal to ensure that USP standards aid practitioners in their delivery of quality care to patients. Particularly in light of the public health emergency involving adulterated heparin in 2008, USP and FDA are continuing to work closely together to help ensure that heparin delivery is as safe and accurate as possible."

The process to change the labeling requirement began with posted Interim Revision Announcements for Heparin Sodium Injection and for Heparin Lock Flush Solution on May 1, 2012 and September 4, 2012, respectively, for public comment in *Pharmacopeial Forum*—the free-access, online vehicle through which USP proposes new and revised standards. The revised heparin monographs will become official on May 1, 2013, at which time all drug products affected by this change will need to be in compliance with the standard. Posting of the official monographs in the "Official Text" section of USP's website (www.usp.org/usp-nf/official-text) will occur on January 25, 2013.

Healthcare professionals must be vigilant during the transition period when old labels and revised labels for heparin sodium injections and heparin lock flush solutions both may appear in the marketplace. Old heparin labels may display only "strength per mL," whereas the revised heparin labels will display both total drug content as "strength per total volume (total mL)" followed in close proximity by "strength per mL."

For additional information on USP's revisions to labeling requirements for Heparin Sodium Injection and Heparin Lock Flush Solution, go to: http://uspgo.to/heparin-labeling-revisions.

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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. **FY1318**

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