



U.S. Pharmacopeia
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New Standard for Labeling on Injectable Medications Designed to Reduce Likelihood of Patient Death, Disability

*Errors in Administration of Injectable Medications in Hospitals,
Other Healthcare Settings Have Been Implicated in Episodes of
Severe Patient Harm*

Rockville, Md., August 4, 2010 — To reduce the likelihood of patient death and disability resulting from errors in the administration of injectable medications in hospitals and other healthcare settings, the U.S. Pharmacopeial Convention (USP) is advancing new labeling requirements that will standardize the information permitted on the highly visible area of these vials to only cautionary statements intended to prevent imminent life-threatening situations. For medications in which no cautionary statement is necessary, this area of the vial will be required to remain blank, precluding company logos, company names and other information from being printed in these locations.

“The situations in which injectable products are often administered to patients can be very busy, such as emergency rooms or intensive care units,” said Roger L. Williams, M.D., chief executive officer of USP. “The new requirements being announced today are intended to make it more likely that doctors, nurses, pharmacists and other healthcare practitioners using injectable products will be able to better see and act on labeling statements that convey important safety messages critical for the prevention of life-threatening situations that may result from the misadministration of a product.”

Reports from the Institute of Medicine, the National Coordinating Council for Medication Error Reporting and Prevention, the Institute for Safe Medication Practices and others have indicated that labeling of injectable products may be linked to medication errors in the administration of these products. Patient safety data from U.S. hospitals have indicated that the most severe medication errors for injectable products were predominantly related to human performance deficits, occurring most often at the time of administration, with environmental distractions as the major contributing factor.

The new requirements apply to the top (circle) surface of the ferrule and cap overseal of a vial containing an injectable medication. Injectable product containers are designed to hold a drug product in a closed, sterile environment, and allow a needle entry through an elastomeric closure (or stopper) to remove the medication. The stopper is connected to a vial by a metal or plastic wrap, which is called the “ferrule.” Over the ferrule and stopper, there is a disc, typically plastic, that protects the stopper; this is called the “cap overseal.” To administer an injectable product, a practitioner must remove the cap overseal, wipe the stopper with an alcohol swab and then insert a needle through the stopper, which sits inside the ring of the ferrule.

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According to the Food and Drug Administration (FDA), if manufacturers believe they need to include a cautionary statement about an imminent life-threatening situation on the ferrule or cap overseal of their product, manufacturers will need to provide a rationale to FDA for why the situation addressed in the statement is considered to be life threatening. Other information will still be permitted to appear elsewhere on the medication vials.

USP is the official standards-setting body for medicines and their ingredients in the United States. USP standards are enforceable by the FDA. The new requirements were approved by USP's Nomenclature Expert Committee, comprising independent experts, following a public comment period open to manufacturers, practitioners, consumer groups and all other interested parties.

For more information, please visit www.usp.org/USPNF/notices/ferrulesCapOverseals.html. To view an image of labeling on ferrules and cap overseals, visit www.usp.org/images/bottleCapWarnings.jpg. Media inquiries may be directed to mediarelations@usp.org.

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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>. **FY1105**