General Chapter <1083> Good Distribution Practices—Supply Chain Integrity Posted for Comment, Workshop Scheduled

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USP is seeking comments on General Chapter <1083> Good Distribution Practices—Supply Chain Integrity, which will appear in Pharmacopeial Forum (PF) 38(2). The new General Chapter is posted here in advance of publication in PF to provide stakeholders adequate time to review and comment before the USP Workshop on Supply Chain Integrity on May 22–23, 2012.

Supply chain integrity involves minimizing risks that arise anywhere along the supply chain, including sourcing pharmaceutical raw materials, manufactured medicinal ingredients, the finished dosage form in its packaging, and distribution to consumers. The goal of good distribution practices is to present sound business practices that help deter unauthorized access to and manipulation of these materials, and to provide effective means for detecting adulterated drug components and drug products (finished medicines) so that they do not enter the supply chain. This General Chapter describes a set of recommended practices to ensure supply chain integrity for drug components and drug products as they move through their supply chain.

The Supply Chain Integrity Workshop will be held on May 22–23, 2012 at USP's Rockville, MD headquarters. The Workshop will provide a forum for discussing public comments related to General Chapter <1083>, offering industry insights and conveying information on future USP initiatives related to supply chain integrity. Additional information on the Workshop can be found at www.usp.org/events-training/workshops/past-workshops.

The deadline for submitting comments on proposals in PF 38(2) is May 31, 2012. Comments should be submitted to Desmond Hunt, Ph.D., Senior Scientific Liaison, (301-816-8341 or dgh@usp.org).

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