

August 30, 2011,

## **FDA Safety Announcement: H & P Industries Povidone Iodine Swabsticks, Prep Solutions, Scrub Solutions, and Prep Gel: Recall - Inadequate Microbial Testing**



**AUDIENCE:** Pharmacy, Consumer, Risk Manager

**ISSUE:** H & P Industries and FDA notified health professionals and the public of a recall of all lots (lots beginning with 8J-8M, 9A-9M, 0A-0M, 1A-1C) of Povidone Iodine Swabsticks, Prep Solutions, Scrub Solutions, and Prep Gel. H & P Industries, Inc. manufactured these Povidone Iodine products without having in place a system for microbial testing at the time of release, without having a system for testing of incoming components, and without having procedures designed and established to prevent objectionable microorganisms in these drug products. Patients undergoing medical and surgical procedures, including those who are immunocompromised, have a high risk of infection from antiseptic surgical preparations that have been prepared, packaged, or held under insanitary conditions. This recall has been initiated at the request of the FDA.

**BACKGROUND:** Povidone Iodine Swabsticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel are labeled as an antiseptic for preparation of the skin prior to surgery, and are used to prevent infection in minor cuts, scrapes and burns. The Povidone Iodine Scrub solutions are labeled also for use as a surgical hand scrub for health care professionals. The Povidone Iodine products were distributed nationwide to healthcare customers. The swabsticks are packaged in individual packets of 1 or 3 swabs and the Prep Solution, Scrub Solution and Prep Gel are sold in bottles.

**RECOMMENDATION:** Specific customers distributing the product and selling it at the wholesale and hospital level are being notified by e-mail with instructions on how to return the product. Consumers that have any of these types of products in their possession should not use the product and should return it to the place it was purchased.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of this product to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Read the MedWatch safety alert, including a link to the FDA recall notice, at:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm269800.htm>

[www.kcercoalition.com/alerts.htm](http://www.kcercoalition.com/alerts.htm)