Indiana State Department of Health
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Mitchell E. Daniels, Jr.
Governor

Gregory N. Larkin, M.D., F.A.A.F.P.
State Health Commissioner

DATE: August 26, 2011

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

DLG

FROM: A. Scott Gilliam, MBA, CP-FS
Director, Food Protection Program

SUBJECT: H&P industries, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; ALL LOTS (Lots beginning with 8J-8M, 9A-9M, 0A-0M, 1A-1C)of Povidone Iodine Swab sticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled were distributed in the State of Indiana. The Povidone Iodine products were distributed nationwide to healthcare customers. The swab sticks are packaged in individual packets of 1 or 3 swabs and the Prep Solution, Scrub Solution and Prep Gel are sold in bottles. Detail information is not available at this time. In addition, if any recalled products are found, please notify this office at 317-233-7360.

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Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.

H&P Industries, Inc. Issues a Voluntary Recall of All Lots of Povidone Iodine Swab sticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel

Contact:
Consumer:
262-538-2907

Returns:
recall.coordinator@handpindustries.com

FOR IMMEDIATE RELEASE - August 24, 2011 - H&P industries, Inc., a manufacturer of over-the-counter drug products has initiated a voluntary recall of ALL LOTS (Lots beginning with 8J-8M, 9A-9M, 0A-0M, 1A-1C)of Povidone Iodine Swabsticks, Povidone Iodine Prep Solutions, Povidone Iodine Scrub Solutions, and Povidone Iodine Prep Gel manufactured by H&P Industries, Inc. This recall has been initiated at the request of FDA.

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. Although H&P Industries, Inc.'s investigation and extensive testing **did not** find contamination, and the products met H&P Industries, Inc., finished goods specifications, H&P Industries, Inc. is voluntarily recalling all Povidone Iodine Products due to and in accordance with the Consent Decree of Condemnation, Forfeiture, and Permanent Injunction entered in the Eastern District of Wisconsin (Civil No. 2:11-cv-00319-AEG) on June 13, 2011.

Povidone Iodine Swab sticks, 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. Patients undergoing medical and surgical procedures, including those who are immune compromised, have a high risk of infection from antiseptic surgical preparations that have been prepared, packaged, or held under insanitary conditions whereby they may have been rendered injurious to health. H&P Industries, Inc. has **not ever** received reports of adverse events or contamination attributed to these Povidone Iodine products.

The Povidone Iodine products were distributed nationwide to healthcare customers. The swab sticks are packaged in individual packets of 1 or 3 swabs and the Prep Solution, Scrub Solution and Prep Gel are sold in bottles.

These products were distributed in the United States. 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. Consumers with questions can call H&P Industries, Inc. at 262-538-2907 Monday through Friday between the hours of 8:30 A.M. and 4:00 P.M. Central Time.

CUSTOMERS WHO DIRECTLY PURCHASED PRODUCT FROM H&P SHOULD NOT RETURN THE PRODUCT ON YOUR OWN. Email H&P Industries, Inc. at recall.coordinator@handpindustries.com to make all return arrangements. Returns will be processed once recall acknowledgements and/or a notice of destruction have been received.

Adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- **Online**:www.fda.gov/medwatch/report.htm[1]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: www.fda.gov/MedWatch/getforms.htm[2]. Mail to address on the pre-addressed form.
- **Fax**: 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food & Drug Administration.

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