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: March 21, 2011

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

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

ASG

SUBJECT: H&P industries, Inc. Recall

SUGGESTED ACTION: **Unclassified Recall; ALL LOTS of POVIDINE PREP PADS are non-sterile and contain some of the same raw material as the recalled Alcohol Prep pads; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled may have been distributed in the State of Indiana. Povidine Iodine Prep Pads are used to prevent infection in minor cuts, scrapes and burns and are labeled as an antiseptic for preparation of the skin prior to surgery. They were distributed nationwide to healthcare customers and are packaged in individual packets and sold in a box of 100 packets. 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 Nationwide Recall of All Lots of Povidine Iodine Prep Pads Due to Potential Microbial Contamination

Contact:
Customer Service
262-538-2900

FOR IMMEDIATE RELEASE — March 15, 2011 —Hartland, Wisconsin, H&P industries, Inc., a manufacturer of over-the-counter products has initiated a voluntary product recall of ALL LOTS of POVIDINE PREP PADS manufactured by H&P Industries, Inc. but which are private labeled for many accounts. This recall has been initiated due to results of the FDA's ongoing investigation and sampling efforts, and H&P Industries, Inc. internal investigation.

The Povidine Iodine Prep Pads are non-sterile and contain some of the same raw material as the recalled Alcohol Prep pads, and were therefore investigated by FDA and by H&P Industries for potential contamination with objectionable organisms. However, analytical testing showed the presence of objectionable organisms, namely *Elizabethkingia meningoseptica*.

We are therefore taking immediate action to voluntarily recall the Povidine Iodine Prep Pads. Use of contaminated Povidine Prep Pads could lead to life-threatening infections, especially in at risk populations, including neonates, immune suppressed patients, and surgical patients. Treatment options are limited for *Elizabethkingia meningoseptica* infections. To date we have not received any reports of adverse events.

Povidine Iodine Prep Pads are used to prevent infection in minor cuts, scrapes and burns and are labeled as an antiseptic for preparation of the skin prior to surgery. They were distributed nationwide to healthcare customers and are packaged in individual packets and sold in a box of 100 packets. ***The affected Povidine Iodine Prep Pads can be identified by the names listed below in their packaging:***

Cardinal Health
Medical Specialties
VHA
Triad
Triad Plus
North Safety
Total Resources

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 certified mail with instructions on how to return the product. If a consumer has any of these types of products in their possession, they should not use the product and should return it to the place it was purchased for a full refund or call H&P Industries, Inc. Customer Service Monday through Friday between the hours of 8:30 **a.m.** and 4:00 **p.m.** Central Time: 262.538.2900.

DO NOT RETURN THE PRODUCT ON YOUR OWN, simply call H&P Industries, Inc. Customer Service listed below and we will issue you a return authorization number and make all return arrangements.

Adverse reactions or quality problems experienced with the use of this product 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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RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]

Recalled Product Photos Are Also Available on FDA's Flickr Photostream.[6]