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: January 7, 201 1

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

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

SUBJECT: Triad Group Recall

SUGGESTED ACTION: **Unclassified Recall; ALL LOTS of ALCOHOL PREP PADS, ALCOHOL SWABS, and ALCOHOL SWABSTICKS manufactured by Triad Group; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the products being recalled may be distributed in the State of Indiana. They were distributed nationwide to retail pharmacies and are packaged in individual packets and sold in retail pharmacies in a box of 100 packets. The affected Alcohol Prep Pads, Alcohol Swabs and Alcohol Swabsticks can be identified by either "Triad Group," listed as the manufacturer, or the products are manufactured for a third party and use the names listed below in their packaging:

Cardinal Health, PSS Select, VersaPro, Boca/ Ultilet, Moore Medical, Walgreens, CVS, Conzellin

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.

Triad Group Issues a Voluntary Nationwide Recall of All Lots of Alcohol Prep Pads, Alcohol Swabs, and Alcohol Swabsticks Due to Potential Microbial Contamination

Contact:
Eric Haertle, COO
262-538-2900

FOR IMMEDIATE RELEASE - January 5, 2011 - Hartland, Wisconsin, Triad Group, a manufacturer of over-the-counter products has initiated a voluntary product recall involving **ALL LOTS** of ALCOHOL PREP PADS, ALCOHOL SWABS, and ALCOHOL SWABSTICKS manufactured by Triad Group but which are private labeled for many accounts to the consumer level. This recall involves those products marked as STERILE as well as non-sterile products. This recall has been initiated due to concerns from a customer about potential contamination of the products with an objectionable organism, namely *Bacillus cereus*. We are, out of an abundance of caution, recalling these lots to ensure that we are not the source of these contamination issues.

Use of contaminated Alcohol Prep Pads, Alcohol Swabs or Alcohol Swabsticks could lead to life-threatening infections, especially in at risk populations, including immune suppressed and surgical patients. To date we have received one report of a ***non***-life-threatening skin infection.

Alcohol Prep Pads, Alcohol Swabs and Alcohol Swabsticks are used to disinfect prior to an injection. They were distributed nationwide to retail pharmacies and are packaged in individual packets and sold in retail pharmacies in a box of 100 packets. **The affected Alcohol Prep Pads, Alcohol Swabs and Alcohol Swabsticks can be identified by either "Triad Group," listed as the manufacturer, or the products are manufactured for a third party and use the names listed below in their packaging:**

Cardinal Health
PSS Select
VersaPro
Boca/ Ultilet
Moore Medical
Walgreens
CVS
Conzellin

These products were distributed in the United States, Canada and Europe.

Specific customers distributing the product and selling it at the wholesale, hospital and retail pharmacy level have been 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 listing "Triad Group" as the manufacturer, they should not use the product and should return it to the place it was purchased for a full refund or call Triad Group 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 the Triad Group 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**:http://www.fda.gov/MedWatch/report.htm[9]
- **Regular Mail**: use postage-paid, pre-addressed Form FDA 3500 available at: http://www.fda.gov/MedWatch/getforms.htm[10] 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.