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 10, 2012

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

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

SUBJECT: DUKAL Corporation Recall

SUGGESTED ACTION: **Unclassified Recall; Nationwide recall of selected lots of benzalkonium chloride swabs and antiseptic wipes manufactured for DUKAL by Jianerkang Medical Dressing Co. Benzalkonium chloride antiseptic wipes are sold separately over-the counter and in kits due to concerns about potential microbial contamination with Burkholderia cepacia; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the recalled products may have been distributed in the State of Indiana. Benzalkonium chloride antiseptic wipes are sold separately over-the counter and in kits. 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.

OTC DRUG Nationwide Recall --Important Information About

Benzalkonium Chloride Antiseptic Wipes

Contact:
1-800-243-0741
productsupport@dukal.com.
Fax: 1-800-FDA-0178

FOR IMMEDIATE RELEASE - July 25, 2012 - Today, DUKAL Corporation announced a U.S. voluntary nationwide recall of selected lots of benzalkonium chloride swabs and antiseptic wipes manufactured for DUKAL by Jianerkang Medical Dressing Co. Benzalkonium chloride antiseptic wipes are sold separately over-the counter and in kits.

This recall is being initiated due to concerns about potential microbial contamination with Burkholderia cepacia. All customers are advised to discontinue use of products identified in this recall immediately as their use could lead to infections, some of which pose certain health risks in immune-suppressed patients. For average healthy people, the presence of Burkholderia cepacia on the swab is not likely to cause serious health risks.

To date, there have been no reported incidents involving these products. In an abundance of caution, we are voluntarily recalling these products to prevent any such potential risk. All customers should dispose of the product. All distributors and kit packers, who include benzalkonium chloride swabs or antiseptic wipes as a component in their kits, should discontinue use of the product and initiate a sub-recall to their customers. All distributors and kit packers should return product in their inventories to DUKAL. These products were distributed nationwide to the wholesale and retail levels.

DUKAL is deeply committed to providing high quality, reliable products and issues this recall as a precaution to ensure consumer safety. DUKAL continues to work closely with FDA to ensure our products meet or exceed FDA requirements.

Instructions

This voluntary recall is for the following BZK product lot numbers:

Items	Description	Put Up
0204	Zee Antiseptic Swabs, Med 2ply	50/box, 36box/case
0271	Zee Antiseptic Swab, Med 2 ply	100/bx, 20bx/cs
854	Dukal BZK Swab Med. 2 ply NS	1/pch200/bx20bx/cs
02040	Zee Antiseptic Swab, Med 2 ply	50/box 36bx/cs
2633	Zee Antiseptic Swab, Med, 2ply	10/bx,10bx/bdl,6bdl/cs
854-1000	Dukal BZK Swab Med. 2 ply NS	1/pch1000/bx4bx/cs

Items	Lot No.
0204	JT14509
0204	JT15209
0204	JT20609
0204	JT20909
0204	JT23709
0204	JT27809
0204	JT32809
0204	JT00710

0204	JT15810
0204	JT18310
0204	JT18810
0204	JT23210
0204	JT25810
0204	JT27610
0204	JT31510
0204	JT35610
0204	JT35911
0204	JT04811
0204	JT05311
0204	JT11811
0204	JT15211
0204	JT15911
0204	JT18211
0204	JT21511-1
0204	JT26311
0204	JT30711
0204	JT22011-1
0204	JT01012
0204	JT04112
0204	JT06512
0204	JT07512
0271	JT14509
0271	JT15209
0271	JT21409
0271	JT20609
0271	JT22009
0271	JT00710
0271	JT18810
0271	JT23210
0271	JT35911
0271	JT05311
0271	JT11811
0271	JT26311
0271	JT01012
854	JT00610
854	JT14511
854	JT22011
854	JT30711
02040	JT14509
02040	JT15209
02040	JT20609
02040	JT15209
02040	JT23709
02040	JT27809
02040	JT00710
02040	JT18310
02040	JT18810
02040	JT23210

02040	JT27610
02040	JT31510
2633	JT14509
2633	JT15209
2633	JT21209
2633	JT27809
2633	JT12510
2633	JT15810
2633	JT18310
2633	JT11811
2633	JT13211
2633	JT15911
2633	JT35911
2633	JT01012
2633	JT30711
854-1000	JT34808
854-1000	JT08209
854-1000	JT15209
854-1000	JT32809
854-1000	JT00610
854-1000	JT27610
854-1000	JT05311
854-1000	JT08011
854-1000	JT18211
854-1000	JT22711-1
854-1000	JT26411
854-1000	JT01012
854-1000	JT01411
854-1000	JT14611
854-1000	JT29011
854-1000	JT01212

This voluntary recall is for BZK products still within product expiration date.
For more information, regarding this voluntary recall and whether to dispose of or return the product, the customer support team can be reached Monday to Friday from 8:30 am to 5:30 pm Eastern time at 800.243.0741. Emails may be sent to productsupport@dukal.com.
Any adverse reactions or quality problems experienced with the use of these products may be reported to the FDA's Med Watch Adverse Events 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 FDA3500 available at www.fda.gov/MedWatch/getforms.htm[2]
- **Fax:** 1-800-FDA-0178

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

RSS Feed for FDA Recalls Information[3] [what's this?[4]]

Photo: Product Labels[5]