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Interim Director

State of California—Health and Human Services Agency
California Department of Public Health



EDMUND G. BROWN JR.
Governor

March 22, 2011

AFL 11-28

TO: All Facilities

SUBJECT: H & P Industries, Inc., the Manufacturer of Povidine/Povidone-Iodine Prep Pads: Recall Due to Potential Microbial Contamination

The California Department of Public Health is requesting action based on an urgent message from the FDA. The FDA has requested “you immediately remove all Povidine-Iodine Prep Pads from your inventory due to a voluntary recall by H & P Industries, Inc., a manufacturer of over-the-counter products. The FDA notified healthcare professionals and patients of the recall involving all lots of Povidine-Iodine Prep Pads manufactured by H&P Industries, Inc. but sold as private labels at the consumer level. This recall has been initiated due to concerns about potential contamination of the products with the pathogenic bacterium *Elizabethkingia meningoseptica*. This recall involves those products marked as STERILE as well as non-sterile products. Use of contaminated Povidine-Iodine Prep Pads could lead to life-threatening infections, especially in at-risk populations including neonates, immune suppressed patients, and surgical patients. *Elizabethkingia meningoseptica* infections are resistant to most common antibiotics and treatment options are limited.

BACKGROUND: Povidine-Iodine Prep Pads are used to disinfect prior to medical invasive intervention. 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 Povidine-Iodine Prep Pads can be identified under several different distributors’ names, including Amerinet, Cardinal Health, Versapro/Medical Specialties, Novation/VHA, Triad, Triad Plus, North Safety and Total Resources. Please see the FDA web site www.fda.gov for more information.

RECOMMENDATION: If a consumer has any of these Povidine-Iodine Prep Pads in their possession listing Amerinet, Cardinal Health, Versapro/Medical Specialties, Novation/VHA, Triad, Triad Plus, North Safety and Total Resources or H&P Industries, Inc. as the manufacturer, they should not use the product and should return it to the place it was purchased for a full refund. Customers with questions should call Triad Group Customer Service at 1-262-538-2900, ext 2680.

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

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- 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.

Thank you for your prompt attention.

Sincerely,

Original Signed by Pamela Dickfoss

Pamela Dickfoss
Acting Deputy Director
Center for Health Care Quality

Attachment: Povidine-Iodine Prep Pad Recall from H&P Industries, Inc.



March 16, 2011

URGENT

OTC DRUG PRODUCT RECALL

This is to inform you of an OTC product recall involving **Povidone Iodine Prep Pads**, manufactured by H&P Industries, Inc. (distributed by Triad Group).

This recall has been initiated due to concerns expressed by the Food and Drug Administration regarding the potential contamination of these products with an objectionable organism, *Elizabethkingia meningoseptica*. H&P's internal investigation also concluded a raw material component as the potential source of this contamination. This investigation was conducted as a result of the earlier ipa pad recall. Both the pvp and ipa pads use this common component.

This recall extends to all Lots of **Povidone Iodine Prep Pads** remaining within their labeled expiration dating (three years), including all Lot numbers beginning with the digits 8, 9, 0 or 1. We began shipping the Lots of product subject to this recall in March 2008.

Please immediately examine your inventory and quarantine product subject to recall – any stock of Povidone Iodine Prep Pads. The affected Povidone Iodine Prep Pads can be identified by the labels listed below.

Item #AC-3201 Amerinet
Item #04-3201 Cardinal Health
Item# 06-3201 Versapro/Medical Specialties
Item# 08-3201 Novation /VHA
Item #10-3201 Triad
Item# 11-PP32 Triad+
Item #PL-3533 Total Resources
Item#PL-3534 North Safety

In addition, if you have further distributed this product, please notify the consignees at once of this product recall. Your notification to your customers may be enhanced by including a copy of this recall notification letter. This recall should be carried out to the user level. Your assistance is appreciated and necessary to prevent potential patient harm.

Please complete and return the enclosed acknowledgment form as soon as possible.

If you have any questions please call H&P Industries Customer Service Monday through Friday, between the hours of 8:30 A.M. and 4:00 P.M. Central Time: 262-538-2900 ext 2680.

This recall is being made with the knowledge of the Food and Drug Administration.

Yours truly,
Pamela Vaughan
Quality Director
H&P Industries, Inc.