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: September 29, 2010

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

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

SUBJECT: Pfizer Consumer Healthcare Recall

SUGGESTED ACTION: **Unclassified Recall; ThermaCare HeatWraps Menstrual product after finding a potential for a leak of the components contained in the wrap; Recommend notification of affected stores via phone, fax or e-mail.**

From the information provided by FDA, the product being recalled may be distributed in the State of Indiana. The recalled product was distributed in United States and Puerto Rico's retail stores. 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.

Pfizer Consumer Healthcare Issues Voluntary Recall of One Lot of ThermaCare HeatWraps Menstrual Product

FOR IMMEDIATE RELEASE – September 24, 2010 – Madison, NJ – Pfizer Consumer Healthcare, a business of Pfizer, Inc., announced today a voluntary recall of one lot of its

ThermaCare HeatWraps Menstrual product distributed in the United States and Puerto Rico.

The company said it is taking this precautionary step after finding a potential for a leak of the components contained in the wrap, which could cause skin injury such as irritation or burn. The issue is limited to the recalled lot. No other ThermaCare products are impacted. Pfizer has notified the U.S. Food and Drug Administration.

The lot number of the products involved is:

Lot #	Exp. Date	Product Name
E06831	8/2012	ThermaCare HeatWraps Menstrual

This lot number is listed on both the outer carton and the foil pouch. The lot number may be followed by either an S or an N. For more information on the recall and where to find this information on the package please visit www.thermacare.com[9] or call 1-800-323-3383, Monday through Friday, 9am to 5pm est.

Pfizer Consumer HealthCare is removing the product in question from store shelves and asking consumers who have purchased and are still in possession of the affected product to record the lot number, throw the product away in its entirety without opening the foil pouch, and call 1-800-323-3383 for replacement.
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 [10]
- Regular Mail: use postage-paid FDA form 3500 available at: www.fda.gov/MedWatch/getforms.htm[11].
- Mail to MedWatch 5600 Fishers Lane, Rockville, MD 20852-9787
- Fax: 1-800-FDA-0178

Photos: Product Labels[12]