Pfizer Inc. Issues A Voluntary Nationwide Consumer Level Recall of One Lot of ThermaCare® Back Pain Therapy HeatWraps, up to 16HR pain relief, Due To Out of Specification Results for High Cell Temperature

Friday, April 26, 2019 - 10:16am

New York, NY, April 26, 2019 – Pfizer Consumer Healthcare, a division of Pfizer Inc., is voluntarily recalling one lot of **ThermaCare® Back Pain Therapy HeatWraps, up to 16HR pain relief**, to the consumer level. Pfizer Consumer Healthcare initiated this recall due to the potential that a HeatWrap could include cells that have a higher cell temperature than specified.

The use of a wrap with a cell with increased temperature poses a potential risk of skin injuries such as burns/blisters and/or skin irritation on the wrap applied area. The product label recommends the user to stop use or wear a layer of clothing if the product feels too hot to prevent skin injuries.

ThermaCare® Back Pain Therapy HeatWraps provide heat therapy for temporary relief of minor muscular and joint aches and pains associated with overexertion, strains, sprains, and arthritis.

The ThermaCare® Back Pain Therapy HeatWraps, up to 16HR pain relief, master lot impacted is S97473, UPC 305733010037 (Lower Back and Hip Therapy, 2 count carton) and was used in the manufacturing of 17 retail display case sub lots.

ThermaCare® HeatWraps Retail Display Information

Carton/Pouch Master Lot Number Retail Display Lot Number Retail Display SKU Retail Display UPC S97473 7216LB F00573171336 305731713367 S97473 7216LA F00573171336 305731713367 S97473 7199JB F00573171373 305731713732 S97473 7199JA F00573171373 305731713732 S97473 7195EA F00573301003N 305731713732 S97473 7195EB F00573301003N 305731713732 S97473 7188NB F00573171516 305731715163 S97473 7188NA F00573171516 305731715163 S97473 7207SA F00573171403 305731714036 S97473 7207SB F00573171403 305731714036 S97473 7206SA F00573171403 305731714036 S97473 7205SA F00573171403 305731714036 S97473 7201SB F00573171403 305731714036 S97473 7202SA F00573171403 305731714036 S97473 7200SB F00573171403 305731714036 S97473 7201SA F00573171403 305731714036 S97473 7200SA F00573171403 305731714036
This master lot and display case sub lots were distributed nationwide to retailers, wholesalers and distributors in the United States and Puerto Rico from June 2017 through March 2018.

Pfizer Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process.

Pfizer Consumer Healthcare is notifying consumers of this recall with this public notification. Wholesalers, distributors and retailers with an existing inventory of the lot being recalled should stop use and distribution and quarantine the product immediately. Wholesalers, distributors and retailers who have further distributed the recalled product should notify any accounts or additional locations which may have received the recalled product from them. For retailer instructions on returning product or additional assistance, call Stericycle at 1- 800-805-3093 between the hours of 8 a.m. to 5 p.m. ET, Monday through Friday.

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 discontinue use of the product, record the lot number, throw the product away in its entirety without opening the foil pouch, and to please contact the Pfizer Consumer Healthcare Information Line at 1-800- 323-3383 (Mon-Fri, 9am-5pm EST) for replacement or reimbursement. Note: The lot number can be found on the side of ThermaCare cartons and on the back of ThermaCare pouches.

If consumers have questions regarding this recall or to report an adverse event or product complaint, contact the Pfizer Consumer Healthcare Information Line at 1-800-

323-3383 (Mon-Fri, 9am-5pm EST).

Consumers should contact their healthcare provider if they have experienced any problems that may be related to using this product.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report **Online:** www.fda.gov/medwatch/report.htm **Regular Mail or Fax:** Download form www.fda.gov/MedWatch/getforms.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.

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

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Media Contact: Kim Bencker 610-329-1340