Pfizer Inc. Issues A Voluntary Nationwide Consumer Level Recall Of Six Lots Of ThermaCare® HeatWraps Due To Leaking Wraps with the Potential For Skin Injuries

Monday, November 26, 2018 - 09:56am

FOR IMMEDIATE RELEASE- New York, N.Y., November 26, 2018 – Pfizer Consumer Healthcare, a division of Pfizer Inc., is voluntarily recalling six lots of **ThermaCare® HeatWrap** product to the consumer level. Pfizer Consumer Healthcare initiated this recall because product from these lots has a potential to leak ingredients that are contained in the heat cell wrap.

The use of a leaking/damaged heat cell wrap could cause skin injuries such as burns/blisters and/or skin irritation on the wrap applied area. The product label warns not to use the product if heat cell contents leak and/or the wrap is damaged or torn.

ThermaCare® Muscle Pain Therapy provides heat therapy for temporary relief of minor muscular aches and pains associated with overexertion, strains, sprains, and arthritis. ThermaCare® Menstrual Pain Therapy provides heat therapy for temporary relief of minor menstrual cramp pain and associated backaches.

The ThermaCare® HeatWrap lots impacted are S68516 (Muscle Pain Therapy 3+1 count carton), T26686 (Muscle Pain Therapy 3 count carton), T26691 (Menstrual Pain Therapy 3 count carton), T26693 (Menstrual Pain Therapy 3+1 count carton); and 8054HA and 8054HB (11 count bundled packages contain one (1) package of Muscle Therapy

Heatwraps, 8HR (3 Count) and two (2) packages of Joint Therapy Heatwraps, 8HR (4 Count)). Please note ThermaCare® Joint Therapy Heatwraps, 8HR are not subject to this recall notification.

These lots were distributed nationwide to retailers, wholesalers and distributors in the United States, Puerto Rico and the U.S. Virgin Islands from September 2017 through August 2018.

ThermaCare® HeatWrap Lot and Packaging Information

Product Name Lot Number Expiry Date SKU UPC Configuration /Count Muscle Pain Therapy 8HR S68516 2020-07 F00573301314 305733013144 3 + 1 one-time use wraps per carton Muscle Pain Therapy 8HR T26686 2020-07 F00573301303C 305733013038 3 one-time use wraps per carton Muscle Pain Therapy 8HR T26691 2020-07 F0057332002H 305733020029 3 one-time use wraps per carton Muscle Pain Therapy 8HR T26693 2020-08 F00573302044 305733020449 3 + 1 one-time use wraps per carton

Bundled Lots

Product Name Bundled Lot Number Carton/ Pouch Lot Number Expiry Date SKU UPC Configuration/ Count Joint/Muscle Pain Therapy 8HR 8054HA T26686 2020-07 F00573301311 305733013113 ulti-pack 11 one-time use wraps per carton Joint/Muscle Pain Therapy 8HR 8054HB T26686 2020-07 F00573301311 305733013113 ulti-pack 11 one-time use wraps per carton

Pfizer Inc. places the utmost emphasis on patient safety and product quality at every step in the manufacturing and supply chain process. Product Name Bundled Lot Number Carton/ Pouch Lot Number Expiry Date SKU UPC Configuration/ Count Joint/Muscle Pain Therapy 8HR 8054HA T26686 2020-07 F00573301311 305733013113 Multi-pack 11 one-time use wraps per carton Joint/Muscle Pain Therapy 8HR 8054HB T26686 2020-07 F00573301311 305733013113 Multi-pack 11 one-time use wraps per carton Pfizer Consumer Healthcare is notifying consumers of this recall with this public notification. Pfizer Consumer Healthcare has already notified its retailers of this recall on October 2, 2018 and has provided instructions for the return of any recalled product. 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 products, 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 numbers 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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