Pfizer Consumer Healthcare

URGENT: Medical Device Recall

November 27, 2018

Notice: **Consumer Level Recall**

ThermaCare® Heatwraps

Product Name	Lot Number	Expiration Date	SKU	UPC	Configuration/Count
Muscle Pain Therapy 8HR	S68516	2020-07	F00573301314	0573301314	3 + 1 one-time use wraps per carton
Muscle Pain Therapy 8HR	T26686	2020-07	F00573301303C	0573301303	3 one-time use wraps per carton
Menstrual Pain Therapy 8HR	T26691	2020-07	F0057332002H	0573302002	3 one-time use wraps per carton
Menstrual Pain Therapy 8HR	T26693	2020-08	F00573302044	0573302044	3 + 1 one-time use wraps per carton

Dear Pfizer Consumer Healthcare Customer:

This letter is to inform you of the **Consumer Level** recall. Pfizer Consumer Healthcare previously released a letter dated October 2, 2018 for the above referenced lots of **ThermaCare® Muscle Pain Therapy Heatwraps, 8HR;** and **ThermaCare® Menstrual Pain Therapy Heatwraps, 8HR** to **retail outlets**.

Pfizer Consumer Healthcare initiated this Consumer Level recall due to a potential for leakage of the ingredients contained in the heat wrap. The use of a leaking/damaged heat cell wrap poses a potential risk to the heat cell ingredients coming in direct contact with the skin which 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 wrap is damaged or torn. The potential risk to patient arising from this issue is considered to be medium.

Pfizer Consumer Healthcare is also voluntarily recalling two (2) lots of bundled ThermaCare® products (refer to Table 2) containing Muscle Pain Therapy Product Lot T26686 and Joint Pain Therapy product. These two (2) bundled package 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.

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Table 2

Product Name	Bundled Lot Number	Carton/Pouch Lot Number	Expiration Date	SKU	UPC	Configuration/Count
Joint/Muscle Pain Therapy 8HR	8054HA	T26686	2020-07	F00573301311	0573301311	Multi-pack 11 one-time use wraps per carton
Joint/Muscle Pain Therapy 8HR	8054HB	T26686	2020-07	F00573301311	0573301311	Multi-pack 11 one-time use wraps per carton

FEDERAL REGULATION 21 CFR 7.49 (d) RESPONSIBILITY OF RECIPIENT STATES: "CONSIGNEES THAT RECEIVE A RECALL COMMUNICATION SHOULD IMMEDIATELY CARRY OUT THE INSTRUCTIONS SET FORTH BY THE RECALLING FIRM ..." PFIZER INC RECOMMENDS THAT YOU RESPOND TO THIS RECALL, EVEN IF YOU DO NOT HAVE THE RECALLED PRODUCT. TO RESPOND, COMPLETE THE REQUESTED INFORMATION ON THE ENCLOSED POSTAGE-PAID, BUSINESS REPLY CARD (BRC) AND RETURN IT TO US, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 1-800-805-3093 (Mon.-Fri. 8 am-5 pm EST).

The recall of the above referenced lots of **ThermaCare® Heatwraps** is directed to the **Consumer**.

Instructions for Retailers/Wholesalers:

In keeping with a consumer level recall we request you please **post the enclosed press release** at the cash register or other prominent location. Our records indicate that you may have received shipment of the affected lot(s) between **September 2017 and August 2018**. Please check your stock immediately against the table above. If you have any of the affected product in your inventory, please stop distribution immediately and promptly return it to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 4317 using the enclosed pre-paid UPS label. If you received this notification without the prepaid UPS label and BRC, require additional shipping labels, or have questions regarding the return procedure, please contact Stericycle Inc. at 1-800-805-3093. You will receive credit from Pfizer Consumer Healthcare **only for the affected lot numbers.**

If you have further distributed any of this lot to other subaccounts, please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request that they immediately cease distribution of the affected lot and promptly return the product to you for credit. Subsequently, you should contact Stericycle Inc. at 1-800-805-3093 for instructions on returning the recalled product you receive from your subaccounts.

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration. We appreciate your immediate attention and cooperation, and sincerely regret any inconvenience this action may cause you. If you have any questions regarding the product, please contact the Pfizer Consumer Healthcare Information Line at 1-800-323-3383 (Mon.-Fri. 9 am-5 pm EST).

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.

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

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- 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>

Sincerely,

Lisa D Paley

Lisa Paley
U.S. Chief Customer Officer
Pfizer Consumer Healthcare

Enclosure: *ThermaCare® Press Release; November 2018*

Pfizer Consumer Healthcare

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

FOR IMMEDIATE RELEASE-New York, NY, 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
Menstrual Pain Therapy 8HR	T26691	2020-07	F0057332002H	305733020029	3 one-time use wraps per carton
Menstrual 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	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 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. 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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Retailer: Please post this notice for no less than 30 days from the date on this notice.