PRODUCT RECALL

Date:	10/8/2018
Manufacturer:	Pfizer Consumer Healthcare
Product:	Article #: 16182 Thermacare Joint/Muscle Pain Therapy 8HR.
Lot Codes:	• Bundled Lot #: 8054HA and 8054HB • Carton/Pouch Lot #: T26686
Dates Sold:	September 2017 through August 2018
Expiration Date:	2020-07

Consumers with questions may contact Pfizer Consumer Healthcare at 1-800-323-3383, Monday - Friday, 9 am - 5 pm (ET).

Post Until: 4/8/2019

Pfizer Consumer Healthcare

URGENT: Medical Device Recall

October 2, 2018

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:

Pfizer Consumer Healthcare is voluntarily recalling the above referenced lots of Thermacare® Muscle Pain Therapy Heatwraps, 8H; and Thermacare® Menstrual Pain Therapy Heatwraps, 8HR, 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.

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 referenced lots of Thermacare® Heatwraps is being conducted to the **Retail level.**

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 5276 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
- 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 Paley
U.S. Chief Customer Officer
Pfizer Consumer Healthcare