October 15, 2018

URGENT RECALL INFORMATION
ThermaCare Menstrual Pain Therapy Heat Wraps
MacGill Item #968586

Dear Valued MacGill Customer,

Pfizer Consumer Healthcare has notified Moore Medical of an Urgent Medical Device Recall regarding a specific lot of the ThermaCare Menstrual Pain Therapy Heat Wraps. This recall has been issued due to a potential leakage of the ingredients contained in the heat wrap.

The lot number affected in this recall is: **#T26691**.

Moore Medical records show this item was received by MacGill to distribute to our customers during the time period of September 1, 2017 through August 31, 2018. Our records indicate you ordered MacGill #968586 during this time period. We urge you to check your supplies immediately to verify the lot number.

If you are in possession of the recalled heat wraps, please contact MacGill Customer Service at 1-800-323-2841 to arrange for a replacement or credit and to return the affected product.

Thank you.

Sincerely,

MacGill School Nurse Supplies

mooremedical
Supporting Health & Care

URGENT MEDICAL DEVICE RECALL

October 8, 2018

Dear Valued Moore Medical Customer:

Pfizer Consumer Healthcare has notified Moore Medical of an Urgent Medical Device Recall regarding specific lots of their Thermacare Heatwraps. This notice has been issued due to a potential for leakage of the ingredients contained in the heat wrap. Affected product first shipped September 1, 2017.

This Urgent Medical Device Recall is being done with the knowledge of the Food and Drug Administration.

For clinical inquiries, please contact Pfizer Consumer Healthcare at **(800) 323-3383**.

A review of our records indicates that you or your company may have purchased items included in this notification. Carefully review the information in this letter and follow the instructions provided below.

Refer to the table below for a list of affected item(s) and lot number(s) distributed by Moore Medical

Moore Medical #	NDC #	Description	Affected Lot(s)	Exp. Date
67994	00573-3020-02	THERMACARE HEAT WRAP MENSTRUAL	T26691	44043

Moore Medical Customer Instructions:

1.) Immediately discontinue use of any product matching the affected item(s) and lot number(s) listed above.

2.) A copy of the Urgent Medical Device Recall from Pfizer Consumer Healthcare has been included for reference.

3.) If you have product affected by this notice, fill out the Moore Medical Reply Form and fax it back (do not mail) to our Regulatory Affairs Department at **866.550.1169.** Detailed product return instructions are provided on the reply form. Please note that credit will only be issued for affected product(s) from the affected lots listed. Replacement items will not be sent. To ensure timely credit to your account and support the completion of this notice, please respond within 30 days.

4.) If you have further distributed any of the item(s) referenced in this notification, provide your accounts with a copy of this notification and request that they return the affected product directly to you.

We sincerely apologize for any inconvenience this product recall may have caused you and your staff. If you have any questions about information provided in this communication, please contact our Regulatory Affairs Department at 800.234.1464 ext. 5407.

Thank you for your prompt attention,

Regulatory Affairs Department
Telephone: 800-234-1464 X5407
Email: MMCregulatoryaffairs@mooremedical.com

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

Pfizer Consumer Healthcare

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 lo 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 AdversetEven 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 D Paley

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