URGENT: DRUG RECALL

August 14, 2019

RELPAX® (eletriptan HBr) tablets

Carton NDC	Lot Number	Expiration Date	Strength	Configuration/Count
0049-2340-45	AR5407	2022 FEB	40 mg	Carton containing 6 tablets (1 blister card x 6 tablets)
0049-2340-05	CD4565	2022 FEB	40 mg	Carton containing 12 tablets (2 blister cards x 6 tablets)

Dear Customer:

Pfizer Inc. (Pfizer) is voluntarily recalling the above referenced lots of **RELPAX® (eletriptan HBr) tablets**. Pfizer initiated this recall because these product lots may not meet Pfizer's in-house microbiological specification. Pfizer completed a Health Hazard Assessment, which concluded that the use of the impacted product has an unlikely probability of being associated with adverse events such as a decrease in therapeutic efficacy or infections in the general population. However, use of the impacted product in certain patient populations may be severe to life-threatening. The potential risk to a patient arising from this issue is considered to be low for the general population and high for immunocompromised patients.

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 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 BUSINESS REPLY CARD (BRC) AND RETURN IT, AS DIRECTED, WITHIN FIVE (5) BUSINESS DAYS. If you have any questions about responding to this letter, please contact Stericycle Inc. at 877-225-9750 (Mon.-Fri. 8 am-5 pm ET).

The recall of the above referenced lots of **RELPAX® (eletriptan HBr) tablets** is being conducted to the **Patient level**.

Instructions for Wholesalers, Retailers, Hospitals and Health Care Providers:

Our records indicate that you received shipment of one or more of the affected product lots, which were distributed from June 2019 to July 2019. Please check your stock immediately against the table above. If you have any of the affected lots in your inventory, please stop distribution immediately and promptly return the product to Stericycle Inc.; 2670 Executive Drive, Suite A; Indianapolis, IN 46241; Attn: Event 7581 using the enclosed pre-paid UPS label. **All returns are requested to be completed within six months of this notice date**. 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 877-225-9750.

If you have further distributed any of the affected product lots to other accounts, please conduct a sub-recall to those accounts and communicate this recall information immediately. Please request your accounts to immediately cease distribution of the affected lots and promptly return the product directly to the above Stericycle Inc. address. Your accounts do not need to fill out a BRC; however, if they have inventory of the

affected lots, they can contact Stericycle Inc. at 877-225-9750 to obtain pre-paid shipping labels for product returns. Further authorization is not required for product returns.

If the affected product lots have been dispensed to patients, please notify these customers regarding this recall.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Pfizer Customer Service Representative at 800-533-4535 (Mon.-Fri. 8 am-5:30 pm ET).

If you received free product through the Pfizer Patient Assistance Program (PAP) or the Pfizer Institutional Patient Assistance Program (IPAP), please check your stock immediately against the table above. If you have any of the affected product lots in your inventory, please follow the instructions above for returning the product to Stericycle Inc. Additionally, if you are aware of any patients to whom you dispensed the affected lots who still may have the product in stock, please ask them to return the product to you and then follow the instructions above for returning the product to Stericycle Inc. To request replacement product for any Pfizer PAP or Pfizer IPAP product you return, please contact 833-203-2776 (Mon.-Fri. 8 am-6 pm ET).

Instructions for Patients:

Patients who are taking this product should consult with their health care provider or pharmacy to determine if they have the affected product lots. Patients with the affected lots should return the product to their pharmacy or contact Stericycle Inc. at 877-225-9750 for instructions on how to return their product and obtain reimbursement for their cost.

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 this recall, please call the appropriate contact center below.

Contact Center	Contact Information	Area of Support
Pfizer Medical Information	800-438-1985, option 3 (Mon.-Fri. 9 am-5 pm ET)	For medical questions regarding the product
Pfizer Drug Safety	800-438-1985, option 1 (24 hours a day; 7 days a week)	To report adverse events and product complaints
Stericycle Inc.	877-225-9750 (Mon.-Fri. 8 am-5 pm ET)	For product returns and reimbursement questions

Sincerely,

Lou Dallago
Vice President U.S. Trade Group

Front View Cartons for 40 mg RELPAX® (eletriptan HBr) tablets