GREENSTONE
A Pfizer Company

100 Route 206 North
Peapack, NJ 07977
Ph: 800.447.3360
FAX: 800.211.3775

URGENT: DRUG RECALL

September 19, 2018

Glipizide XL

(Glipizide) Extended-Release Tablets

NDC	Lot Number	Expiration Date	Strength	Configuration/Count
59762-0541-2	T71137	FEB 2022	5 mg	24 bottles/Shipper 500 tabs/bottle

Dear Customer:

Greenstone LLC, a wholly owned subsidiary of Pfizer Inc, is voluntarily recalling the above referenced lot of **Glipizide XL** due to the potential presence of particulate matter. Pfizer has completed a Health Hazard Assessment which concluded that there is an unlikely probability of occurrence of adverse events. There have been no reports of adverse events associated with this affected lot. The potential risk to a patient arising from this issue is considered to be negligible.

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 ..." GREENSTONE LLC 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, 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 ET).

The recall of the above referenced lots of **Glipizide XL** is being conducted to the **Retail level**.

Our records indicate that you may have received shipment of the affected lot which was distributed from March 2018 through April 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 4994 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 1-800-805-3093.

If you have further distributed this lot, 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 directly to the above Stericycle Inc. address. Your accounts do not need to fill out a

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BRC; however, if they have inventory of the affected product, they can contact Stericycle Inc. at 1-800-805-3093 to obtain pre-paid shipping labels for product returns. Further authorization is not required for product returns.

Reimbursement for the returned product will be made by credit memorandum. If you have any questions regarding the reimbursement, please contact your Greenstone Customer Service Representative at 1-800-447-3360 (Mon.-Fri. 8 am-5:30 pm ET).

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 medical questions regarding the product, please contact Medical Information at 1-800-438-1985 (Mon.- Fri. 8 am-7 pm ET).

Sincerely,

Brendan O'Leary
General Manager