# RECALL NOTIFICATION

September 21, 2001

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| PRODUCT INFORMATION | Greenstone brand Glyburide Tablets, 1.25 mg, bottle of 100<br>NDC: 59762-3725-1<br>Lot Numbers: 37DYR, 84DTF<br><br>Greenstone brand Glyburide Tablets, 2.5 mg, bottle of 100<br>NDC: 59762-3726-3<br>Lot Numbers: 40FCW, 42FCW, 44FCW, 46FCW, 76DWD, 88DTF<br><br>Greenstone brand Glyburide Tablets, 5 mg, bottle of 100<br>NDC: 59762-3727-4<br>Lot Numbers: 18FTH, 19FTH, 18FTD, 39FTD, 17FTH, 93FRY, 95FRY, 96FRY, 57FJD, 58FJD, 14FJX, 75FKR, 74FKR, 44FMD, 60FJD<br><br>Greenstone brand Glyburide Tablets, 5 mg, bottle of 500<br>NDC: 59762-3727-6<br>Lot Numbers: 43FKW, 85FMU, 86FMH<br><br>Greenstone brand Glyburide Tablets, 5 mg, bottle of 1000<br>NDC: 59762-3727-7<br>Lot Numbers: 12FTH, 61FJD, 11FMF, 59FMD, 15FJX, 17FJX, 18FKS, 16FKS, 15FKS, 22FKS, 19FKS, 07FMF, 10FMF, 28FMK, 02FJX, 17FKS |
| REASON | Greenstone Limited is voluntarily recalling the above-mentioned products. An investigation by Greenstone has detected the presence of fungal organisms in some lots of Glyburide tablets. The source of the fungal organisms was traced to a raw material used in the formulation. As a result, Greenstone has voluntarily initiated a recall of the above product lots. |
| POTENTIAL RISK | Based on a literature review, the fungi/molds detected, such as Paecilomyces, Aspergillus, and Penicillium, have in rare cases caused infection via inhalation (sinus or lung infection) or via entry through damaged skin (cellulitis). The fungi/molds detected may cause difficult to treat infections in immuno-compromised patients such as diabetics and HIV and renal transplant patients who also have diabetes. We are aware of no cases of infection associated with eating or swallowing these fungi. Patients who may inquire about this recall should be urged to continue taking their existing medication until a replacement is obtained, to avoid any potential loss of blood sugar control. |

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| ACTION | **It is important that you carry out these instructions.** FDA regulations (21 CFR Part 7.49) state: "Consignees that receive a recall communication should immediately carry out the instructions set forth by the recalling firm…"<br><br>1. Discontinue using, dispensing and distributing these lots and promptly return any inventory according to the instructions below.<br>2. Perform a physical count of your inventory of the recalled Glyburide products and complete the enclosed Reply Card and Packing Slip.<br>3. Mail the postage paid Business Reply Card **even if you do not have any recalled product.**<br>4. <u>If you are a wholesaler</u> and have distributed any of the recalled lots, please contact your retail accounts, advise them of the recall, and instruct them return the product to the address below.<br>5. <u>If you are a wholesaler</u> and have sold any of these lots to another wholesaler, please contact them and instruct them to carry out the actions listed above. |
| RETURN OF RECALLED PRODUCT | Use the shipping label provided and return the product with the packing slip to:<br><br>Greenstone Limited<br>Attn: Unit 4959-41-030<br>2605 E. Kilgore, Dock C<br>Kalamazoo, MI 49001<br><br>Direct customers will receive credit for the following:<br>1. Returned product will be valued at the last published price unless purchased at contract prices offered by Greenstone. Only recalled product will be reimbursed.<br>2. Associated shipping charges.<br>3. Notification costs will be reimbursed at $1.32 per customer that received the recalled lot.<br>4. Handling costs will be reimbursed at reasonable and customary levels determined by Greenstone.<br><br>Customers that purchased the recalled product through a wholesaler should also return the product to the above address. Credit will be issued through the wholesaler, as identified on the Reply Card, only for recalled product.<br><br>Please allow 6-8 weeks for processing. To help assure prompt issue of credit, do not include any other product with your return. |
| OTHER INFORMATION | This recall is being conducted with the knowledge of the Food and Drug Administration. No other Greenstone products are affected by this recall. If you have any questions regarding this recall, please call 1-800-323-4204, 8:00 AM to 5:00 PM EST. We appreciate your cooperation and sincerely regret any inconvenience caused by this action. |