



Chandrika Lucki
Authorized U.S. Agent
Graviti Pharmaceuticals Private Limited,
Freyr, Inc.
150 College Road West, Suite 102
Princeton, NJ 08540

April 5, 2024

Re: Docket No. FDA-2024-P-0105

Dear Ms. Lucki:

This letter responds to your citizen petition received on January 4, 2024, requesting that the Food and Drug Administration (FDA) determine whether Glucotrol (glipizide) Tablets 5 milligrams (mg) and 10 mg, approved under the new drug application 017783, held by Pfizer Inc., have been discontinued and withdrawn for safety or effectiveness reasons.

FDA has reviewed its records and determined that Glucotrol (glipizide) Tablets 5 mg and 10 mg, were not withdrawn from sale for reasons of safety or effectiveness. Thus, FDA will maintain Glucotrol (glipizide) Tablets 5 mg and 10 mg, in the “Discontinued Drug Product List” section of *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (240) 402-9917.

Sincerely,

Swati V.
Rawani -S

Digitally signed by
Swati V. Rawani -S
Date: 2024.04.05
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Swati Rawani
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure