Date: January 3, 2024

To,

Division of Dockets Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane
Room 1061, HFA-305
Rockville, MD 20852

From,

Chandrika Lucki
Authorized US Agent,
Graviti Pharmaceuticals Private Limited,
Freyr, Inc. 150 College Road West, Suite
102, Princeton NJ – 08540, USA
Phone #: +1 908 483 7958; Ext #: 3002
Mobile # + 1 7326484326; Fax #: +1 866 486 6883
Email: L.chandrika@FreyrSolutions.com

CITIZEN PETITION

Product Name: Glipizide Tablets USP, 5 mg and 10 mg

Respected Sir / Madam,

The undersigned submits this petition on behalf of Graviti Pharmaceuticals Private Limited (Graviti) accordance with 21 C.F.R. §§ 10.25 and 10.30, and pursuant to Sections 505(j) and 505(w) of the Federal Food, Drug, and Cosmetic Act ("FDC Act") and 21 C.F.R. §§ 314.122 and 314.161 to request that the Food and Drug Administration ("FDA") determine whether a listed drug was not discontinued and withdrawn for safety or effectiveness reasons.

GLUCOTROL (glipizide) tablets, 5 mg and 10 mg, are the subject of NDA 017783, held by Pfizer Inc., and initially approved on May 8, 1984. GLUCOTROL designated as RLD in Orange Book database and is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

While referring the orange book database, we noticed that, Reference Listed Drug (RLD, NDA # N017783) GLUCOTROL (Glipizide) Tablets, 5 mg and 10 mg, of PFIZER INC is currently under discontinued status. But **Federal Register determination that product was not discontinued or withdrawn for safety or effectiveness reasons** statement has not been assigned. The orange book database provided as **Attachment I** for ready reference**.**

Hence, Graviti Pharmaceuticals Private Limited submitted a Control Correspondence # 00159426 on April 04, 2023 and response received from the Agency on May 04, 2023. Agency suggested to submit an abbreviated new drug application (ANDA) accompanied by (at the same

time as the ANDA submission) a citizen petition under 21 CFR 10.25(a) and 10.30 seeking a determination whether the listed drug has been withdrawn from sale for safety or effectiveness reasons. The copy of Control Correspondence # 00159426 cover letter and Agency's response letter are provided as **Attachment II.**

A. ACTIONS REQUESTED

Petitioner requests that FDA determine whether Glucotrol (glipizide) Tablets, 5 mg and 10 mg, approved under New Drug Application ("NDA") number 017783, held by Pfizer Inc., has been not discontinued or withdrawn for safety or effectiveness reasons.

B. STATEMENT OF GROUNDS

Under the FDC Act, an Abbreviated New Drug Application ("ANDA") must rely on FDA's approval findings for a Reference Listed Drug ("RLD"). See FDC Act § 505(j)(2). If a listed drug has ceased to be offered for sale by its manufacturer, a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was not withdrawn for reasons of safety or effectiveness. See 21 C.F.R. §§ 314.122 and 314.161. If FDA determines that the listed drug was withdrawn from sale for reasons of safety and effectiveness (or if FDA withdraws or suspends NDA approval for reasons of safety or effectiveness), then the drug listing is removed from the Orange Book. See id. § 314.162. If FDA determines that the listed drug was not withdrawn from sale for reasons of safety and effectiveness, then the drug listing remains in the Orange Book and may be cited in an ANDA as a RLD.

The Orange Book currently identifies Glucotrol Tablets, 5 mg and 10 mg, approved on May 08, 1984 under NDA 017783, in the "Discontinued Drug Product List" section of the Orange Book. FDA appears to have moved NDA 017783 (5 mg & 10 mg) to the "Discontinued Drug Product List" in the May 2022 Cumulative Supplement to the Orange Book.

As per the current Orange Book database, there are several ANDAs approved for 5 mg and 10 mg and are currently in Active state.

Petitioner is not aware of any information indicating that the withdrawal was made for safety or effectiveness reasons and believes the discontinuation of Glucotrol Tablets, 5 mg and 10 mg, under NDA 017783 was due to only commercial considerations.

Graviti requests that FDA determine that Glucotrol Tablets, 5 mg and 10 mg, approved under NDA 017783, was not withdrawn for reasons of safety or effectiveness.

C. ENVIRONMENTAL IMPACT

Petitioner claims a categorical does not require under 21 C.F.R. § 25.31.

D. ECONOMIC IMPACT STATEMENT

Petitioner will, upon request by the Commissioner, submit economic impact information, in accordance with 21 C.F.R. § 10.30(b).

E. CERTIFICATION

The undersigned certifies that, to the best knowledge and belief of the undersigned, this Petition includes all information and views on which the Petition relies, and that it includes representative data and information known to the Petitioner that are unfavorable to the Petition.

Sincerely,

L.Chandrika@freyrsolutions.com
Digitally signed by L.Chandrika@freyrsolutions.com
Date: 2024.01.03 16:32:39 +05'30'

Chandrika Lucki,
Authorized US Agent for Graviti Pharmaceuticals Private Limited, India.
The US agent letter of appointment is provided as **Attachment-III**