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

August 17, 2019

CITIZEN PETITION

Dear Sir or Madam:

The Harman Finochem Limited submits this petition, pursuant to Federal Food, Drug, and Cosmetic Act ("FD&C Act") 21 C.F.R. §10.25(a) & § 10.30 and in accordance with 21 C.F.R. § 314.12 & 314.161, requesting the Commissioner of Food and Drug Administration to provide a determination on whether a listed drug has been voluntarily withdrawn for safety or effectiveness reasons as outlined below.

A. Action Requested

The Petitioner requests that the Commissioner of the Food and Drug Administration to Confirm that the Reference Listed Drug (RLD), Glucophage®, NDA 020357 held by BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE was not withdrawn from sale for safety or effectiveness reasons.

B. Statement of Grounds

Under the FDC Act 505(j)(2), an ANDA must rely for safety and effectiveness on a Reference Listed Drug (RLD). As per 21 CFR 314.122 and 314.161, 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a person wishing to submit an ANDA for the drug must petition FDA for a determination of whether the drug was withdrawn for reasons of safety or effectiveness.

Also, as per 21 CFR 314.162, if FDA determines and withdraws a listed drug from sale for reasons of safety and efficacy, then the drug listing is removed from the Orange Book. However, if FDA determines that the listed drug was withdrawn from sale not for the reasons of safety and efficacy, then it remains listed in the Orange Book and may be cited in an ANDA as an RLD.

The Orange Book lists the Glucophage®, NDA 020357 held by BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE as RLD with the market-status as

discontinued in the Orange Book. Currently, the Orange book lists ANDA 090564 of Granules India Ltd. the Reference standard (RS) for Metformin Hydrochloride Tablets, 1 g.

Petitioner is further unaware of any reason why Glucophage®, NDA 020357 may have been removed from sale while other ANDA holders for generic Glucophage® are still in the market. Therefore the petitioner believes that the discontinuation of Glucophage®, NDA 020357 was due to commercial considerations. Petitioner requests FDA to confirm that the NDA holder for Glucophage®, NDA 020357 has not withdrawn the product for reason of safety or effectiveness.

C. Environmental Impact

In Accordance with the requirements set forth in 21 C.F.R. § 25.31 (a), the petitioner hereby requests a Categorical Exclusion from the requirements to prepare an Environmental Impact Assessment.

D. Economic Impact Statement

The 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, which is unfavorable to the petition.

Sincerely,

Navneet Malpani

Digitally signed by Navneet Malpani
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Navneet Malpani,

Regulatory Affairs (Formulation)

	Petitioner	**US Agent**
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