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

July 25, 2020

CITIZEN PETITION

Dear Sir or Madam:

The Harman Finochem Limited, hereby submits this petition, pursuant to the Federal Food, Drug and Cosmetics Act ("FD&C Act") and in accordance with 21 CFR § 10.25(a) and 10.30 requesting the Commissioner of the Food and Drug Administration to designate an additional reference standard (RS) for Metformin Hydrochloride Extended Release Tablets, 750 mg in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) since the current RS i.e. Metformin Hydrochloride Extended Release Tablets, 750 mg (ANDA 078596) by Amneal Pharmaceuticals NY LLC is not available in the market.

A. Action Requested

The petitioner respectfully requests the Commissioner of the Food and Drug Administration to designate a suitable alternative reference standard to enable Harman to complete the evaluation of in-vivo Bioequivalence studies of a potential generic product for which product development process has been completed.

B. Statement of Grounds

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits any person to submit to the Food and Drug Administration an ANDA to seek approval to market a generic drug. To obtain approval of an ANDA for a generic drug, an ANDA applicant first must identify the previously approved drug product it seeks to duplicate, i.e., the reference listed drug (RLD). A reference standard (RS) selected by FDA is the specific drug product that the ANDA applicant must use in conducting any in vivo bioequivalence testing required to support approval of its ANDA.

FDA identifies products listed as RLD and RS in Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book). As per the current electronic Orange Book, Metformin Hydrochloride Extended Release Tablets, 750 mg (ANDA 078596) by Amneal Pharmaceuticals NY LLC is identified as the RS. However, though not listed as 'Discontinued' in the Electronic Orange Book, this product is currently unavailable for sale as per FDA Updates and Press Announcements on NDMA in Metformin dated June 11, 2020 (Refer Attachment 1).

The petitioner has also contact multiple suppliers to obtain the RS samples but failed get those samples due to above specified reason (Refer Attachment 2).

In view of the above, Harman is unable to complete the evaluation/comparison of its generic product. The Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions, Section III.C.2 and Section 111.C.3, states as follows:

'FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the discontinued RLD and is the market leader based on units sold.'

'If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard.'

Hence, the petitioner respectfully requests the Commissioner to designate a suitable alternative reference standard to enable development of a generic version of the subject drug product.

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)

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