



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

August 21, 2020

Pooja Kulkarni  
General Manager, Regulatory Affairs  
Macleods Pharmaceuticals Limited  
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Andheri (East), Mumbai – 400093, INDIA

Sent via email to: [poojak@macleodspharma.com](mailto:poojak@macleodspharma.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate a suitable reference standard for purpose of submitting an ANDA application for Metformin hydrochloride extended-release tablets 750 mg with reference to the current electronic orange book database was received by this office on 08/21/2020.

It was assigned docket number FDA-2020-P-1792. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Karen Malvin  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)

CC: Mr. Andrej Gasperlin ([andrejg@macleodspharma.com](mailto:andrejg@macleodspharma.com))