DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

August 19, 2019

Navneet Malpani
Regulatory Affairs (Formulation)
Harman Finochem Limited
107-A Vinay Bhavya Complex, 159 A, CST Road
Kalina Santacruz (East) Mumbai, INDIA 400098

Sent via email to: navneetm@harmanfinochem.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to confirm 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Listed Drug (RLD), Glucophage®, NDA 020357 held by BRISTOL MYERS SQUIBB CO PHARMACEUTICAL RESEARCH INSTITUTE was not withdrawn from sale for safety or effectiveness reasons was received by this office on 08/16/2019.

It was assigned docket number FDA-2019-P-3877. 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 in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Digitally signed by Dynna Bigby
Date: 2019.08.20 11:53:26 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management Staff
FDA/Office of Operations (OO)

CC: Ushma.patel@navitaslifesciences.com