DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

July 27, 2020

Navneet Malpani, Regulatory Affairs
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, govind.srinivasan@navitaslifesciences.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting 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 was received by this office on 07/24/2020.

It was assigned docket number FDA-2020-P-1701. 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 Gorham-bigby -S

Digitally signed by Dynna Gorham-bigby -S
Date: 2020.07.27 12:44:26 -04'00'

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