DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

July 13, 2020

Blessy Johns
US Agent for Aurobindo Pharma Limited
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 08520

Sent via email to: bjohns@aurobindousa.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to designate the approved "Carbidopa and Levodopa Tablets 25 mg / 250 mg (ANDA 078536) of Sun Pharmaceutical Industries, Inc." as a new Reference Standard, upon which ANDA applicant can rely for purpose of *in vivo* bioequivalence testing required for ANDA filing was received by this office on 07/10/2020.

It was assigned docket number FDA-2020-P-1653. 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,

Dynna Gorham-bigby -S
Digitally signed by Dynna Gorham-bigby -S
Date: 2020.07.13 12:48:16 -04'00'

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