**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Food and Drug Administration
Rockville, MD 20857

November 6, 2019

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 a suitable alternative reference standard (RS) for purpose of conducting in vivo bioequivalence studies to support our ANDA application for Amoxicillin and Clavulanate Potassium Extended Release Tablets 1000 mg/ 62.5 mg with reference to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) was received by this office on 11/05/2019.

It was assigned docket number FDA-2019-P-5237. 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,

Karen Kennard -S

Digitally signed by Karen Kennard -S
Date: 2019.11.06 14:04:27 -05'00'

Karen Kennard
Director
Dockets Management Staff
FDA/Office of Operations (OO)