DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 4, 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 for purpose of conducting in vivo bioequivalence studies to support our ANDA application for Phenoxybenzamine Hydrochloride Capsules USP, 10 mg with reference to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) was received by this office on 04/04/2019.

It was assigned docket number FDA-2019-P-1607. 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: 2019.04.04 14:05:15 -04'00'

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)