U.S. FOOD & DRUG ADMINISTRATION

April 24, 2020

Blessy Johns
US Agent for Aurobindo Pharma Limited
Aurobindo Pharma USA, Inc.
279 Princeton-Hightstown Road
East Windsor, NJ 080520

Re: Docket No. FDA-2019-P-5237

Dear Ms. Johns:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition received on November 5, 2019. Your petition requests that the Agency designate a suitable alternative reference standard (RS) for purpose of conducting *in vivo* bioequivalence studies to support your ANDA application for Amoxicillin and Clavulanate Potassium Extended Release Tables 1000mg/62.5 mg with reference to the current Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations).

FDA has been unable to reach a decision on your petition due to the need to address other Agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Carol Bennett -S

Digitally signed by Carol Bennett -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Carol Bennett -S, 0.9.2342.19200300.100.1.1=2000004958
Date: 2020.04.24 09:57:00 -04'00'

Carol J. Bennett
Deputy Director
Office of Regulatory Policy
Center for Drug Evaluation and Research

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