



**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration  
Silver Spring MD 20993

May 27, 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](mailto:bjohns@aurobindousa.com)

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA designate the approved "Dicloxacillin Sodium Capsules 500 mg (ANDA # 062286) of Teva Pharmaceuticals USA 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 05/27/2020.

It was assigned docket number FDA-2020-P-1427. 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 Bigby  
Supervisory Administrative Proceedings Officer  
Dockets Management Staff  
FDA/Office of Operations (OO)