DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Silver Spring MD 20993

April 3, 2020

Shyam Busireddy, Chief Operating Officer
Belcher Pharmaceuticals, LLC
6911 Bryan Dairy Road
Largo, FL 33777

Sent via email to: shyamb@belcherpharma.com

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting the FDA require that current holders of abbreviated new drug applications for tacrolimus oral capsule drug products demonstrate that those drugs meet the more stringent bioequivalence requirements that the FDA has imposed since their approval and if those products are not bioequivalent then the FDA should change their therapeutic equivalence rating of those ANDAs from "AB" to "BX" was received by this office on 04/02/2020.

It was assigned docket number FDA-2020-P-1247. 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
Digitally signed by Dynna Bigby
Date: 2020.04.03 14:32:56 -04'00'

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