Shyam Busireddy
Chief Operating Officer
Belcher Pharmaceuticals, LLC
6911 Bryan Dairy Road
Largo, FL 33777
Sent via email to:
shyamb@belcherpharma.com

September 23, 2020

Re: Docket No. FDA-2020-P-1247

Dear Mr. Busireddy:

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 April 2, 2020. Your petition requests that the Agency require that current holders of abbreviated new drug applications (ANDAs) for tacrolimus oral capsule drug products demonstrate that those drugs meet more stringent bioequivalence criteria or change the therapeutic equivalence rating of those ANDAs from "AB" to "BX".

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. 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: 2020.09.18 13:18:33 -04'00'

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

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