



Sharif Ahmed
Principal Consultant
Lachman Consultant Services, Inc.
1600 Stewart Avenue
Westbury, NY 11590

Re: Docket No. FDA-2019-P-0198

JUL 08 2019

Dear Mr. Ahmed:

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 January 10, 2019, and submitted on behalf of NaviSci Pte Ltd. Your petition requests that the Agency designate an additional reference standard for Sulfamethoxazole and Trimethoprim Oral Suspension in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).

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