



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

January 11, 2019

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

Sent via email to: LCS@lachmanconsultants.com

Dear Petitioner:

Your submission requesting that the Commissioner of Food and Drug Administration to designate an additional reference standard (RS) for Sulfamethoxazole and Trimethoprim Oral Suspension in the active section of the Orange Book for conducting BE studies to compile and submit an Abbreviated New Drug Application ("ANDA") for this product was received by this office on 1/10/2019.

It was assigned docket number FDA-2019-P-0198. 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,

Karen Kennard

Karen Kennard
Acting Director
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)