U.S. FOOD & DRUG ADMINISTRATION

NOV 15 2019

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

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

Dear Mr. Ahmed:

This letter responds to your citizen petition received on January 10, 2019 (Petition), and submitted on behalf of NaviSci Pte Ltd., requesting that the Food and Drug Administration (FDA or Agency) designate an additional reference standard for sulfamethoxazole and trimethoprim oral suspension, 200 milligrams (mg)/5 milliliters (mL); 40 mg/5 mL, in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (the Orange Book).[1] In the Petition, you state that the reference listed drug (RLD), Bactrim (sulfamethoxazole and trimethoprim) oral suspension, NDA 017560, is in the discontinued section of the Orange Book and that the current reference standard, held by Hi Tech Pharmacal under ANDA 074650, is not available in the market (Petition at 2).

We have investigated your statement that the drug product currently selected as a reference standard, sulfamethoxazole and trimethoprim oral suspension, 200 milligrams (mg)/5 milliliters (mL); 40 mg/5 mL, approved under ANDA 074650 held by Hi Tech Pharmacal, is unavailable. We have determined that there was an increase in the distribution of the current reference standard after your petition was submitted, and that the reference standard product is currently being distributed. Because of the increase in distribution of sulfamethoxazole and trimethoprim oral suspension, 200 milligrams (mg)/5 milliliters (mL); 40 mg/5 mL, approved under ANDA 074650 held by Hi Tech Pharmacal, we dismiss your petition as moot.

Sincerely,

Janet Woodcock, M.D. Acting Director
FOR Director
Center for Drug Evaluation and Research

[1] The Orange Book is available at http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm.

U.S. Food & Drug Administration
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