LACHMAN CONSULTANT SERVICES, INC.
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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January 10, 2019

VIA ELECTRONIC SUBMISSION

Division of Dockets Management
Food and Drug Administration (HFA-305)
Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

Dear Sir or Madam:

Lachman Consultants Services, Inc., ("Lachman") the US Agent for NaviSci Pte Ltd ("NaviSci") hereby submits this petition pursuant to the Federal Food, Drug and Cosmetics Act ("FD&C Act") and in accordance with 21 CFR § 10.25(a) and 10.30 requesting the Commissioner of the Food and Drug Administration to designate an additional reference standard (RS) for Sulfamethoxazole and Trimethoprim Oral Suspension in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) since the current RLD and the RS is not available in the market.

A. Action Requested

The petitioner respectfully requests the Commissioner of the 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.

B. Statement of Grounds

Section 505(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) permits any person to submit to the Food and Drug Administration (FDA or the Agency) an ANDA to seek approval to market a generic drug. In order to obtain approval of an ANDA for a generic drug, an ANDA applicant first must identify the previously approved drug product it seeks to duplicate, i.e., the reference listed drug (RLD), and must show, among other things, that the generic drug is

bioequivalent to the RLD. A RS selected by FDA is the specific drug product that the ANDA applicant rnust use in conducting any in vivo bioequivalence testing required to support approval of its ANDA. All the approved drug products by the FDA are listed in the Orange Book.

In accordance with Section III.C.2 of FDA's draft guidance document, 'Referencing Approved Drug Products in ANDA', "FDA also will consider selecting a new reference standard when the Agency determines that the quantity of the current reference standard in distribution is so limited that a potential ANDA applicant is not able to obtain a sufficient quantity for in vivo bioequivalence testing (even if the current reference standard is not in the Discontinued Section of the Orange Book). When selecting a new reference standard, FDA generally selects a drug product that is therapeutically equivalent to the discontinued RLD and is the market leader based on units sold."

Section III.C.3 of guidance document also states, "If there is a reference standard in the Active Section of the Orange Book but there are limited or no quantities of the reference standard in distribution, or a potential ANDA applicant believes a reference standard other than the one selected by FDA is appropriate, then the potential applicant may submit a citizen petition under 21 CFR 10.25(a) and 10.30 to request that FDA select that different listed drug also as a reference standard."

Currently, the electronic Orange Book identifies BACTRIM® (Sulfamethoxazole and Trimethoprim) Oral Suspension (N017560) as the Reference Listed Drug (RLD) (Attachment 1: Electronic Orange Book search results) in the Discontinued section. Table 1 identifies the other approved products that are identified as active in the Orange Book. Although Hi Tech Pharmacal's Sulfamethoxazole and Trimethoprim, Oral Suspension, 200mg/5ml; 40mg/5ml (A074650) currently designated as the RS is shown as active in the Orange Book, it is not available in the market.

Table 1

Mkt.Status	Active Ingredient	Appl No	Dosage Form	Route	Strength	TE Code	Applicant Holder
RX	SULFAMETHOXAZOLE; TRIMETHOPRIM	A074650	SUSPENSION	ORAL	200MG/5ML; 40MG/5ML	AB	HI TECH PHARMACAL CO INC
RX	SULFAMETHOXAZOLE; TRIMETHOPRIM	A077785	SUSPENSION	ORAL	200MG/5ML; 40MG/5ML	AB	VINTAGE PHARMACEUTICALS LLC
RX	SULFAMETHOXAZOLE; TRIMETHOPRIM	A091348	SUSPENSION	ORAL	200MG/5ML; 40MG/5ML	AB	AUROBINDO PHARMA LTD

Please be informed that, based on the market data (Attachment 2) available from IMS (Information Management System) currently generic versions of Sulfamethoxazole and Trimethoprim Oral Suspension (Application No: A091348) held by AUROBINDO PHARMA LTD appears to be the generic market leader based on units sold.

The lack of availability of the current RS is preventing bioequivalence study in support of NaviSci's Abbreviated New Drug Application. Therefore, the petitioner respectfully requests the Commissioner to designate a marketed, approved generic drug product to be designated as the RS to enable development of a generic version of the subject drug product.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

The petitioner does not believe that this is applicable in this case but will agree to provide such an analysis if requested by the Agency.

E. Certification

The undersigned certifies, that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,

Sharif Ahmed
Digitally signed by Sharif Ahmed
Date: 2019.01.10 10:58:34 -05'00'

Sharif Ahmed
Principal Consultant

Attachment 1: Screenshot of the electric Orange Book search results for Sulfamethoxazole and Trimethoprim, Oral Suspension
Attachment 2: IMS data from October 2014 through October 2018 for Sulfamethoxazole and Trimethoprim, Oral Suspension