John A. Sowards
Member
Admitted in SC

April 4, 2019

Division of Dockets Management
Department of Health and Human Services
Food and drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Citizen Petition

Dear Sir / Madam:

The undersigned submits this petition under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), and in accordance with 21 C.F.R 10.20 and 21 C.F.R 10.30, to request that the Food and Drugs Administration ("FDA") amend the agency's Approved Drug products with Therapeutic Equivalence Evaluations ("Orange book") to designate Neostigmine Methylsulfate Injection, Solution 3 mg/3 mL (1 mg/mL) NDA No. 203629, as Reference Listed Drug ("RLD").

A. Action Requested

The undersigned requests that FDA designates Neostigmine Methylsulfate Injection, Solution 3 mg/3 mL (1 mg/mL), NDA No. 203629, as RLD for the purposes of submitting an ANDA for a generic version of this drug product.

B. Statement of Grounds

According to the FDA, "(a) reference listed drug (21 C.F.R 314.94(a) (3)) means the listed drug identified by FDA as the drug product upon which an applicant relies in seeking approval of its ANDA. A drug company seeking approval to market a generic equivalent must refer to the Reference Listed Drug in its Abbreviated New Drug Application (ANDA)." By designating a reference listed drug as the standard to which all generic versions must be shown to be bioequivalent, FDA hopes to avoid possible significant variations among generic drugs and their brand name counterparts.

In addition, the regulations state that (a)n abbreviated new drug application must refer to a listed drug. Ordinarily, that listed drug will be the drug product selected by the agency as the reference standard for demonstrating bioequivalence Therefore a

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sponsor cannot submit an ANDA for approval unless FDA has selected a reference listed drug to which the sponsor may compare its generic product. "A firm wishing to market a generic version of a listed drug that is not designated as the reference listed drug may petition the Agency through the Citizen Petition procedure (see 21 C.F.R 10.25(a) and 21 C.F.R 10.30).

As per orange book, Fresenuis Kabi USA, LLC's Neostigmine Methylsulfate Injection, Solution 3 mg/3 mL (1 mg/1mL) is the Neostigmine Methylsulfate Injection product with a 3 mL fill volume strength (Please refer Annexure-I & II) approved under NDA No. 203629. Hence we are requesting that Neostigmine Methylsulfate Injection, solution with NDA No. 203629 be recommended for RLD designation, so as to allow filing of a generic application for Neostigmine Methylsulfate Injection 1 mg/mL in a 3 mL fill volume. The current approved labeling for the Neostigmine Methylsulfate Injection for NDA 203629 3 mg/mL is provided under Annexure-III.

C. Environmental Impact

A claim for categorical exclusion of the requirements for an environmental assessment is made pursuant to 21 C.F.R. 25.31.

D. Economic Impact Statement

Pursuant to 21 C.F.R. 10.30(b), Nexsen Pruet 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 that are unfavorable to the Petition.

Sincerely,

John A. Sowards/Member

Enclosures

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Annexure I:

Copy of Orange Book current through March 2019, listing the subject formulation Neostigmine Methylsulfate Injection, Solution 3 mg/3 mL (1 mg/1mL) NDA 203629.

Annexure II:
Copy of Drugs@FDA listing subject formulation Neostigmine Methylsulfate Injection, Solution 3 mg/3 mL (1 mg/1mL) NDA 203629.

Annuxure III:
Copy of current approved FDA labeling for Neostigmine Methylsulfate Injection, Solution 3 mg/3 mL (1 mg/1mL) NDA 203629 dated November 20, 2018.