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April 6, 2020

VIA ELECTRONIC SUBMISSION

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

CITIEN PETITION

Dear Sir / Madam:

The undersigned hereby submits this Citizen Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act ("FDC Act"), and 21 C.F.R. § 314.93, and in accordance with 21 C.F.R. § 10.25(a) and 21 C.F.R. § 10.30, to request that the Food and Drug Administration ("FDA") amend the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") to designate different listed drug also as an additional reference standard.

A. Action Requested

The Petitioner requests that the Commissioner of Food and Drugs designate ALCAINE (Proparacaine Hydrochloride) Ophthalmic Solution 0.5%, ANDA # A080027 held by Alcon Laboratories Inc. as an additional Reference Standard to enable applicants to conduct the comparative studies needed to develop the generic version of Ophthaine (Proparacaine Hydrochloride) Ophthalmic Solution, 0.5% NDA # N008883 held by Apothecon Inc Div Bristol Myers Squibb for ANDA submission.

B. Statement of Grounds

Based on the Section III.C.3 "Requesting Selection of a Reference Standard" in the "*Draft Guidance for Industry – Reference Approved Drug Products in ANDA Submissions,*" issued by FDA in January 2017, an potential applicant "may submit a citizen petition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". The requirement for a potential applicant to submit a citizen petition,

according to the above-mentioned Guidance is that "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".

For the case of Proparacaine Hydrochloride Ophthalmic Solution 0.5%, as shown in the Orange book from FDA website current through March 2020, the RS was assigned by FDA to the product with the ANDA number A040277, which current applicant holder is Akorn Inc.

A copy of the FDA's Approved Drug Products with Therapeutic Equivalency Evaluation (FDA's Orange Book) is included as an **Annex I**.

Since our client is developing an ANDA for this product, our client would need the RS to conduct a comparative studies. Starting from November 2019, we have been informed by the RLD/RS supplier, that Proparacaine Hydrochloride Ophthalmic Solution 0.5% held by Akorn Inc. is in backorder and not available in the US market.

Due to the unavailability of RS product in the US market, the Petitioner believes that it meets the condition that "there are limited or no quantities of the reference standard in distribution", as mentioned as one of the conditions for allowing petition of adding a new RS for the product in the FDA Guidance.

As the latest information that our client has, currently suppliers are distributing the ALCAINE (Proparacaine Hydrochloride) Ophthalmic Solution 0.5% products in the US market.

Additionally, the Petitioner would like to bring Agency's attention that, the ALCAINE (Proparacaine Hydrochloride) Ophthalmic Solution 0.5%, ANDA # A080027 held by Alcon Laboratories Inc. was listed as 'RS' status as per the "38th Edition Cumulative Supplement Number 02 : February 2018 ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST" and later same was delisted by addition of 'RS' status to Proparacaine Hydrochloride Ophthalmic Solution 0.5%, ANDA number A040277 held by Akorn Inc. as per 38th Edition Cumulative Supplement Number 05 : May 2018 ADDITIONS/DELETIONS FOR PRESCRIPTION DRUG PRODUCT LIST.

Excerpt of 38th Edition Cumulative Supplement Number 02: February 2018 additions/deletions for prescription drug product list is included as an **Annex II**.

Excerpt of 38th Edition Cumulative Supplement Number 05: May 2018 additions/deletions for prescription drug product list as an **Annex III**.

Based on above, the Petitioner respectfully requests FDA to designate an additional RS for this product ALCAINE (Proparacaine Hydrochloride) Ophthalmic Solution 0.5%, ANDA # A080027 held by Alcon Laboratories Inc. from available suppliers so that the RS would be available for a potential applicant to perform the comparative studies.

C. Environmental Impact

The Petitioner claims a categorical exclusion of the requirements for an environmental assessment pursuant to 21 CFR § 25.31.

D. Economic Impact Statement

Pursuant to 21 CFR § 10.30(b), 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 that are unfavorable to the Petition.

Sincerely yours,

David L. Rosen, B.S. Pharm., JD

Enclosures:

Annex - I: Copy of Approved Drug Products with Therapeutic Equivalence Evaluations, Electronic Orange Book.

Annex - II: Copy of 38th Edition Cumulative Supplement Number 02: February 2018 additions/deletions for prescription drug product list.

Annex - III: Copy of 38th Edition Cumulative Supplement Number 05: May 2018 additions/deletions for prescription drug product list.