4820 Emperor Blvd
4th Floor
Durham, NC 27703
iqvia.com

Date: December 13, 2019

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

CITIZEN PETITION

Dear Sir Madam,

The undersigned IQVIA RDS Inc., hereby submits this petition, on behalf of a client, 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 Dicyclomine Hydrochloride Capsules in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book) since the current RLD/ RS is not available in the market.

A. Action Requested

The petitioner respectfully requests the Commissioner of the Food and Drug Administration to designate a suitable alternative reference standard to enable our client to proceed with the development of the generic 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 an ANDA to seek approval to market a generic drug. 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). A reference standard (RS) selected by FDA is the specific drug product that the ANDA applicant must use in conducting any in vivo bioequivalence testing required to support approval of its ANDA.

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FDA identifies products listed as RLD and RS in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book). As per the current electronic Orange Book, BENTYL® (dicyclomine hydrochloride) capsules of ALLERGAN SALES LLC (Application No: N007409) is identified as the RLD and RS (Refer **Attachment 1**). However, though not listed as 'Discontinued' in the Electronic Orange Book, this product is currently unavailable for sale as per Current and Resolved Drug Shortages and Discontinuations Reported to FDA (Refer **Attachment 2**).

In view of the above, our client is unable to complete the evaluation/ comparison of its generic product.

The Draft Guidance for Industry, *Referencing Approved Drug Products in ANDA Submissions, Section III.C.2 and Section III.C.3*, states as follows:

"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."

"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."

Market Share Snapshot from January 2018 – June 2019 of Dicyclomine Hydrochloride Capsules USP, 10 mg (provided by IBM Watson Health) is provided in the table below:

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Marketer Name	Market Share by Dose Form
Teva Pharmaceuticals USA	88,680,423
Mylan Pharmaceuticals, Inc.	67,407,289
Lannett Company Inc.	51,474,418
Hikma Pharmaceuticals USA Inc.	43,155,899
Marlex Pharmaceuticals, Inc.	6,725,685
Mylan Institutional, Inc.	599,313
American Health Packaging	4,820
Allergan USA, Inc.	4,145

The petitioner respectfully requests the Commissioner to designate a suitable alternative reference standard to enable development of a generic version of the subject drug product.

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C. Environmental Impact

The Petitioner claims a categorical exclusion from the requirement of an environmental assessment or environmental impact statement pursuant to 21 CFR § 25.31.

D. Economic Impact

Pursuant to 21 CFR § 10.30(b), upon request by the Commissioner, the Petitioner will, submit an economic impact information.

E. Certification

The undersigned certifies that to the best of its knowledge, 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 unfavourable to the petition.

Sincerely,

Digitally signed by Smith, Patti(q805438)
Date: 2019.12.17 15:34:18 -05'00'

Patti Smith

Director, Global Regulatory Affairs,
IQVIA RDS Inc.,
4820 Emperor Blvd-4th Floor
Durham, North Carolina (NC) 27703
USA

Phone No: +1-484-934-6572
Fax No: +1-484-550-6453
Email Address: patti.smith@iqvia.com

Attachments for Agency's ready reference:

Attachment-1: Electronic Orange Book search results showing that BENTYL® Capsules is currently designated as RLD and RS

Attachment -2: Information of Current and Resolved Drug Shortages and Discontinuations Reported to FDA indicating that BENTYL capsules have been discontinued