U.S. FOOD & DRUG ADMINISTRATION

Patti Smith
Director, Global Regulatory Affairs
IQVIA RDS Inc.
4820 Emperor Blvd-4th Floor
Durham, NC 27703

Re: Docket No. FDA-2019-P-5970

Dear Ms. Smith:

This letter responds to your Citizen Petition to the Food and Drug Administration (FDA) received on December 17, 2019 (Petition). The Petition requested FDA to designate a suitable reference standard for dicyclomine hydrochloride capsules in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (the Orange Book).[1]

Your Petition stated that the Orange Book listed BENTYL (dicyclomine hydrochloride) capsules, 10 milligrams (mg), under new drug application (NDA) 007409, held by Allergan Sales LLC as the reference listed drug and the reference standard. The Petition claimed that NDA 007409 is not available on the market in sufficient quantities to allow for bioequivalence testing needed for the development of a generic product.

FDA recently issued responses to two citizen petitions requesting that alternative reference standards be designated for BENTYL (dicyclomine hydrochloride) capsules (docket nos. FDA-2018-P-1869 and FDA-2019-P-3800).[2] In addition, as you may know, the Orange Book recently was updated to list ANDA 084285, held by Lannett Company Inc, as the reference standard for dicyclomine hydrochloride capsules (10 mg), and NDA 007409 was moved to the discontinued section of the Orange Book. Accordingly, your Petition is dismissed as moot.[3]

Sincerely,

Janet Woodcock, MD
Director
Center for Drug Evaluation and Research

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

[2] FDA's combined response for these two citizen petitions is available at https://www.regulations.gov/document?D=FDA-2018-P-1869-0009.

[3] See 21 CFR 10.30(e)(2)(iii).

U.S. Food & Drug Administration
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