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BY ELECTRONIC SUBMISSION

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

Citizen Petition

The undersigned ("Petitioner") submits this Citizen Petition pursuant to the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. §§ 10.25(a) and 10.30 with regard to the FDA-designated Reference Standard ("RS") for Dicyclomine Hydrochloride Capsules, 10 mg. The current RS, approved under New Drug Application ("NDA") 007409, is commercially unavailable. For this reason, Petitioner requests that the Food and Drug Administration ("FDA") take action to maintain a pathway for Abbreviated New Drug Application ("ANDA") submissions. Petitioner requests that FDA designate an additional (or new) RS for Dicyclomine Hydrochloride Capsules, 10 mg, and amend the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") to reflect ANDA 084285 as a RS for the drug.

I. ACTION REQUESTED

Petitioner requests that FDA designate ANDA 084285 (Dicyclomine Hydrochloride Capsules, 10 mg) held by Lannett Co Inc (or another appropriate ANDA) as a RS for purposes of FDA evaluation of ANDAs for Dicyclomine Hydrochloride Capsules, 10 mg.

II. STATEMENT OF GROUNDS

FDC Act § 505(j) allows the marketing of generic versions of previously approved drug products based on FDA approval of an ANDA. To obtain ANDA approval, the applicant must show, among other things, that with respect to a listed drug (i.e., a previously approved drug product), the generic drug product has the same active ingredient(s) in the same strength, dosage form and route of administration, has essentially identical labeling, and is bioequivalent.

A "listed drug" includes a new drug product that has an effective approval under FDC Act § 505(j), that has not been withdrawn or suspended under FDC Act §§ 505(e)(1) through (5) or (j)(5), and that has not been withdrawn from sale for reasons of safety or effectiveness. See 21 C.F.R. § 314.3. Listed drugs are identified in FDA's Orange Book. An RLD is the listed drug

identified by FDA as the drug product on which an ANDA applicant should rely in seeking approval of an application. The product designated by FDA as the "reference standard," in the Orange Book, must be used to conduct the in vivo bioequivalence testing required for FDA approval. However, where there is a "limited or no quantities of the reference standard in distribution" a potential ANDA applicant may request designation of a new RS through the submission of a citizen petition. FDA, *Draft Guidance for Industry, Referencing Approved Drug Products in ANDA Submissions*, at 9 (Jan. 2017).

Despite diligent efforts to obtain sufficient quantities of the present RS—Bentyl (Dicyclomine Hydrochloride Capsules, 10 mg) (NDA 007409)—the drug product is not commercially available and appears to have been discontinued from marketing. As such, Dicyclomine Hydrochloride Capsules, 10 mg, is shielded from additional generic competition.

There is a sound basis for selecting an ANDA—and preferably ANDA 084285—as a new RS. Dicyclomine Hydrochloride Capsules, 10 mg, held by Lannett Co. Inc. (ANDA 084285), appears to lead the U.S. market in terms of the number of capsules sold (as per IMS data), and should therefore be more readily accessible and more appropriate for RS designation.

In an effort to introduce further competition, FDA should designate one of the following ANDAs listed in the Orange Book as the new (or an additional) RS for Dicyclomine Hydrochloride Capsules, 10 mg, and preferably ANDA A084285.

Mkt.Status	Active Ingredient	Proprietary Name	Appl No	Dosage Form	Route	Strength	TE Code	RLD	RS	Applicant Holder
RX	DICYCLOMINE HYDROCHLORIDE	BENTYL	N007409	CAPSULE	ORAL	10MG	AB	RLD	RS	ALLERGAN SALES LLC
RX	DICYCLOMINE HYDROCHLORIDE	DICYCLOMINE HYDROCHLORIDE	A084285	CAPSULE	ORAL	10MG	AB			LANNETT CO INC
RX	DICYCLOMINE HYDROCHLORIDE	DICYCLOMINE HYDROCHLORIDE	A040319	CAPSULE	ORAL	10MG	AB			MYLAN PHARMACEUTICALS INC
RX	DICYCLOMINE HYDROCHLORIDE	DICYCLOMINE HYDROCHLORIDE	A085082	CAPSULE	ORAL	10MG	AB			WATSON LABORATORIES INC
RX	DICYCLOMINE HYDROCHLORIDE	DICYCLOMINE HYDROCHLORIDE	A040204	CAPSULE	ORAL	10MG	AB			WEST WARD PHARMACEUTICAL CORP

Accordingly, the undersigned requests that FDA designate in the Orange Book Dicyclomine Hydrochloride Capsules, 10 mg, approved under one of the above-cited ANDAs (and, in particular, ANDA A084285) as a new RS.

III. ENVIRONMENTAL IMPACT

An environmental assessment report on the action requested in this petition is not required under 21 C.F.R. § 25.31.

IV. ECONOMIC IMPACT

In accordance with 21 C.F.R. § 10.30(b), economic impact information is to be submitted only when requested by the Commissioner following review of the petition. Petitioner hereby commits to promptly provide this information, if so requested.

V. CERTIFICATION

Petitioner certifies that, to the best knowledge and belief of Petitioner, 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 is unfavorable to the petition.

Sincerely,

Kurt R. Karst

KRK/eam