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SUBMITTED VIA REGULATIONS.GOV

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

SUITABILITY PETITION

Dear Sir/Madam:

The undersigned, on behalf of a client, submits this Suitability Petition pursuant to Section 505(j)(2)(C) of the Federal Food, Drug and Cosmetic Act ("FDC Act") and in accordance with 21 C.F.R. § 314.93 and 21 C.F.R. §§ 10.20 and 10.30, to request that the Commissioner of the U.S. Food and Drug Administration ("FDA") declare that the drug product Baclofen Tablets, 15 mg, is suitable for consideration in an Abbreviated New Drug Application ("ANDA").

A. Action Requested

The petitioner requests that FDA declare that Baclofen Tablets, 15 mg, is suitable for submission as an ANDA.[1] As designated in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"), the Reference Listed Drug ("RLD") upon which this petition is based is Novartis Pharmaceuticals Corp.'s LIORESAL (baclofen) Tablets, which is approved for prescription use under New Drug

[1] A Suitability Petition with a similar request was submitted to FDA in June 2019 and remains pending despite the statutory 90-day deadline to rule on such a petition. *See* FDA, Suitability Petition, Docket No. FDA-2019-P-3423 (June 6, 2019), *available at* https://www.regulations.gov/document?D=FDA-2019-P-3423-0001.

Application ("NDA") 017851 in 10 mg and 20 mg strengths.[2] The petitioner seeks to introduce a new 15 mg strength for prescription use.

B. Statement of Grounds

FDC Act § 505(j)(2)(A)(iii) provides for the submission of an ANDA for a drug product that differs in strength from that of the listed drug provided FDA has first approved a petition permitting the submission of such an application.

LIORESAL Tablets approved under NDA 017851 contains either 10 mg or 20 mg of baclofen in a tablet dosage form. A copy of the current Orange Book entry for LIORESAL Tablets (NDA 017851) is included in ***Attachment 1***. The proposed drug product also contains baclofen in a tablet dosage form, but in a 15 mg strength. The petition is thus seeking a change in tablet strength to 15 mg from that of the RLD (10 mg and 20 mg).

The proposed change in strength is consistent with the dosing recommendations in approved labeling for both the RLD and the current Reference Standard, Teva Pharmaceuticals USA, Inc.'s ("Teva's") ANDA 072235 for Baclofen Tablets, 20 mg. For example, the prescribing information for ANDA 072235 provides the following dosing information:

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[2] Both drug products approved under NDA 017851 are listed in the "Discontinued Section" of the Orange Book. In addition, approval of the NDA (for both strengths) has been withdrawn. *See* FDA, Notice, Novartis Pharmaceuticals Corp. et al.; Withdrawal of Approval of 92 New Drug Applications and 49 Abbreviated New Drug Applications, 74 Fed. Reg. 23,407, 23,409 (May 19, 2009). Nevertheless, FDA previously determined that both the 10 mg and 20 mg strengths approved under NDA 017851 were not withdrawn for safety or effectiveness reasons. *See* FDA, Notice Determination That Benztropine Mesylate Tablets and Nine Other Drug Products Were Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 68 Fed. Reg. 46,645, 46,646 (Aug. 6, 2003).

DOSAGE AND ADMINISTRATION

The determination of optimal dosage requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40 to 80 mg daily).

The following dosage titration schedule is suggested:

5 mg t.i.d. for 3 days

10 mg t.i.d. for 3 days

15 mg t.i.d. for 3 days

20 mg t.i.d. for 3 days

Thereafter additional increases may be necessary but the total daily dose should not exceed a maximum of 80 mg daily (20 mg q.i.d.).

The lowest dose compatible with an optimal response is recommended. If benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug (see **WARNINGS,** Abrupt Drug Withdrawal).

Prescribing Information, Baclofen Tablets, ANDA 072235 (Dec. 2019), *available at* https://dailymed.nlm.nih.gov/dailymed/getFile.cfm?setid=5648c772-50cb-4961-996e-e68a8eb699ea&type=pdf; *see also*, Prescribing Information, LIORESAL Tablets (Apr. 1998), *available at* https://dailymed.nlm.nih.gov/dailymed/archives/fdaDrugInfo.cfm?archiveid=422086.

The availability of a new 15 mg intermediate strength is consistent with the dosing instructions for the RLD (NDA 017851) and the Reference Standard (ANDA 072235). Moreover, the availability of a 15 mg strength will provide a prescribing physician with a greater degree of flexibility in achieving proper dosing for a specific patient's needs. The proposed change in strength from that of the RLD does not raise questions of safety or efficacy for the proposed drug product. Therefore, FDA should conclude that clinical investigations are not necessary to demonstrate safety or effectiveness of the proposed drug product and approve both this Suitability Petition and the petition submitted in June 2019 (Docket No. FDA-2019-P-3423).

There are no proposed changes in labeling with the exception of a change in strength sought in this petition. The uses, indications, warnings, and directions for use will remain the same as that of the RLD. Approved labeling for both the RLD, LIORESAL Tablets (NDA 017851), updated in April 1998, and the ANDA Reference Standard, Baclofen Tablets, 20 mg, approved under Teva ANDA 072235 and updated in December 2019, is included as ***Attachment 2***. Draft labeling for the proposed drug product, modeled after the Orange Book-identified Reference Standard (ANDA 072235)

is included as ***Attachment 3***. Therefore, the Petitioner requests that FDA find that a change in tablet strength from 10 mg and 20 mg to 15 mg of baclofen raises no questions of safety or effectiveness.

The Pediatric Research Equity Act ("PREA"), enacted in December 2003, amended the FDC Act by requiring certain applications for a drug submitted under FDC Act § 505 to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is deferred or waived. *See* FDC Act § 505B(a)(1)(A)(i). Specifically, PREA applies to all applications for a new active ingredient, dosage form, indication, route of administration, or dosing regimen. *See id.* ANDAs submitted under an approved suitability petition for a change in strength are not subject to PREA requirements. *See* FDA, Draft Guidance for Industry, How to Comply with the Pediatric Research Equity Act, 4 (Sep. 2005). Petitioner asserts that PREA is not applicable to the proposed Baclofen Tablets, 15 mg, drug product because the proposed change concerns only a new strength. As such, PREA should not serve as an impediment to the Agency granting this petition.

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.

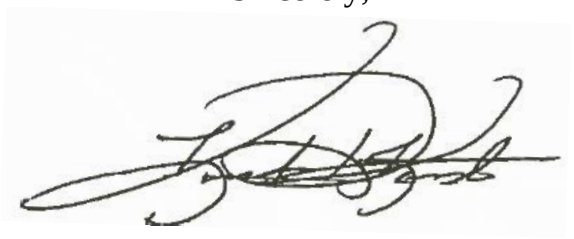
D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic impact information is submitted only when requested by the Commissioner. This information will be promptly provided, if so requested.

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 which are unfavorable to the Petition.

Sincerely,



Kurt R. Karst

KRK/eam
Attachments