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June 06, 2019

Division of Dockets Management
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
Rockville, MD 20852

SUITABILITY PETITION

This Suitability Petition is submitted pursuant to Section 505(j)(2)(c) of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.93, in in accordance with 21 CFR 10.20 and 10.30, to request that the Commissioner of the Food and Drug Administration ("FDA") determine and declare that the drug product, Baclofen Tablets, USP, 15mg, is suitable for submission in a supplemental Abbreviated New Drug Application ("sANDA").

A. Action Requested

The petitioner seeks a change of strength (quantitative changes to the active substance of a drug product) as an additional strength to the Reference Listed Drug (RLD) and the Reference Standard (RS) Please refer to the summary table below for additional information:

Applicant Holder	Novartis Pharmaceuticals Corp	Ivax Pharmaceuticals Inc. subsidiary of Teva Pharmaceuticals USA	Oxford Pharmaceuticals, LLC
Application Number	N017851	A077234 (10mg) A072235 (20mg)	A077088
Approved Strengths	10mg and 20mg	10mg and 20mg	10mg and 20mg
Drug Name	Lioresal® (baclofen)	Baclofen	Baclofen
RLD/RS Designation from Orange Book	RLD (Discontinued)	RS (for 20mg only)	Not Applicable
Approval Date	10mg: Prior to Jan 01, 1982 20mg: Jan 20, 2982	10mg: Jul 21, 1988 20mg: Jul 21, 1988	10mg: Oct 31, 2007 20mg: Oct 31, 2007
Additional Strength Requested	Not Applicable	Not Applicable	15mg
Dosage Form	Tablets	Tablets	Tablets
Route of Administration	Oral	Oral	Oral

The petitioner requests that FDA declare Baclofen Tablets, USP, 15mg, suitable for submission via an sANDA.

B. Statement of Grounds

Section 505(j)(2)© of the Federal Food, Drug, and Cosmetic Act and 21 CFR 314.93 allow for the submission of an sANDA for a drug product that differs in strength from the RLD provided that the FDA has approved a suitability petition proposing the filing of such an application.

The proposed drug product will differ only in strength from the currently approved 10mg and 20mg tablet strengths. The indications and usage, dosage and administration, route of administration, dosage form, intended patient population, and recommendations for use will remain the same as that of the RS. There are no proposed changes to the labeling with the exception of changes in strength sought in this petition. Therefore, there will be no difference in the safety and efficacy of the proposed new strength 15mg tablets.

A copy of FDA's Electronic Orange Book for Baclofen is provided in Attachment I. A copy of the Ivax/Teva RS Labeling from DailyMed is provided in Attachment II.

C. Environmental Impact

The petitioner claims a categorical exclusion under 21 CFR 25.31.

D. Economic Impact

Pursuant to 21 CFR 10.30(b), economic impact information will only be submitted if requested by the Commission following review of this petition.

E. Certification

The undersigned certifies that, to the best knowledge of the undersigned, this petition includes all information and views upon which the petition relies and includes representative data and information known to the petitioner which are unfavorable to the petition.

Sincerely,

John Schultz
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Attachments:

I. FDA Electronic Orange Book printout for Baclofen products.
Labeling for Ivax/Teva Baclofen Tablets via DailyMed.