



Pharmobedient Consulting, LLC
642 NE 3rd Ave
Fort Lauderdale, FL 33304
Attn: Anthony LaViola

Sent via email to: anthony@pharmobedient.com

Docket No. FDA-2024-P-1403

Dear Anthony LaViola:

This is in response to your petition received on March 20, 2024, by the U.S. Food and Drug Administration (FDA or Agency), requesting permission to submit an Abbreviated New Drug Application (ANDA) for the following drug product: Dantrolene Sodium Orally Disintegrating Tablets (ODT), 25 mg, 50 mg and 100 mg. The listed drug product to which you refer in your petition is Dantrium (Dantrolene Sodium) Capsules, 25 mg, 50 mg, and 100 mg, approved under NDA 017443 and held by Endo Operations Ltd.

Your request involves a change in dosage form from that of the listed drug product (i.e., from Capsules to Orally Disintegrating Tablets). The change that you request is the type of change that is permissible under section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act), subject to FDA approval of a petition submitted under that section of the Act. However, for the reasons explained below, the Agency denies your request.

We have reviewed your petition under section 505(j)(2)(C) of the Act and FDA's implementing regulations at 21 CFR 314.93. FDA will approve a petition properly submitted under § 314.93 unless FDA finds, among other grounds for denying such a petition, investigations must be conducted to show the safety and effectiveness of the drug product or of any of its active ingredients, its route of administration, dosage form, or strength which differs from the reference listed drug. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(i).

In addition, the Pediatric Research Equity Act (PREA) provides that a person who submits an application or supplement under section 505 for a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration shall submit assessments adequate to evaluate the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation for which the drug is safe and effective, unless this requirement is waived. Section 505B of the Act. If a change proposed in a suitability petition triggers the need for pediatric studies under PREA to assess safety and efficacy in a relevant pediatric subpopulation and FDA does not waive the requirement, the proposed product will not be eligible to be approved in an ANDA and the

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suitability petition must be denied. See section 505(j)(2)(A) of the Act (“The Secretary may not require that an abbreviated application contain information in addition to that required by clauses (i) through (viii) [of Section 505(j)(2)(A)].”). Because you are seeking a change in dosage form, this proposed product triggers PREA.

The Agency has determined that clinical trials are required under PREA to assess safety and efficacy in relevant pediatric subpopulations for the spasticity indication. With respect to the spasticity indication, FDA has found that the proposed drug products could represent a meaningful therapeutic benefit over existing therapies for pediatric patients and that the listed drug to which you refer is not adequately labeled for pediatric use in all relevant pediatric subpopulations. Specifically, the weight-based pediatric dosage titration schedule in the labeling would not allow for the titration schedule to be followed in pediatric patients weighing less than 50 kg. Accordingly, PREA requires that you conduct additional clinical studies to generate necessary labeling for pediatric use in patients under 50 kg.

Therefore, this petition is being denied because clinical trials are required under PREA for the approval of the requested change to the drug product. The request for a waiver of the pediatric study requirements under PREA has been denied. Please contact the Division of Neurology 1 at 301-796-2250 if you wish to pursue approval of your product under section 505(b) of the Act.

If you disagree with our determination concerning the approvability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR 10.20, in the format outlined in § 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the Agency to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.



Sincerely,

William Chong, M.D.
Director
Office of Safety and Clinical Evaluation
for Lilun Murphy, M.D.
Director
Office of Generic Drugs
Center for Drug Evaluation and Research



William
Chong

Digitally signed by William Chong

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