Pharmobedient Consulting, LLC
642 N.E. 3rd Avenue
Fort Lauderdale, FL 33304
Attn: Anthony LaViola

Sent via email to: anthony@pharmobedient.com

Docket No. FDA-2024-P-4134

Dear Anthony LaViola:

This is in response to your petition received on August 24, 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: Diclofenac Potassium Tablets, 37.5 mg. The listed drug product to which you refer in your petition is Cataflam (Diclofenac Potassium) Tablets, 25 mg and 50 mg, approved under NDA 020142 and held by Novartis Pharmaceuticals Corp.

Your request involves a change in strength from that of the listed drug product (i.e., from 25 mg and 50 mg to 37.5 mg). 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, any of the proposed changes from the RLD would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem. See section 505(j)(2)(C) of the Act; 21 CFR 314.93(e)(1)(iv).

The Agency has determined that your proposed change in strength raises questions of safety and effectiveness. The proposed change from the RLD would jeopardize the safe or effective use of the product so as to necessitate significant labeling changes to address the newly introduced safety or effectiveness problem. 21 CFR 314.93(e)(1)(iv).

FDA, therefore, denies your petition to submit an ANDA for the proposed change from the RLD because the requested change to the drug product/your proposed product, Diclofenac Potassium Tablets, 37.5 mg, would, at the least, necessitate significant labeling changes to address the newly introduced safety or effectiveness problem posed by the proposed strength, which differs from the listed drug product. The RLD labeling recommends dosages which range from

100 to 200 mg/day in divided doses, i.e., 50 mg two, three, or four times a day. There is no indication in the RLD labeling for the proposed 37.5 mg dose strength to be used. The proposed change in strength would change the frequency of dosing to achieve the recommended dosing ranges, which is not supported by the labeling and may increase the risk of medication errors. And the additional strength could result in patient and prescriber confusion that a single 37.5 mg tablet is an appropriate and acceptable dose. Please contact the Division of Anesthesiology, Addiction Medicine, and Pain Medicine in the Office of Neuroscience at (301) 796 - 2280 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 Iilun 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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