



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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DEC 17 2003

Taro Pharmaceuticals U.S.A., Inc.
Attention: Avraham Yacobi, Ph.D.
5 Skyline Drive, Suite 3
Hawthorne, NY 10532-2155

Docket No. 03P-0083/CP1

Dear Dr. Yacobi:

This is in response to your petition filed on March 4, 2003, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug products: Carbamazepine Tablets USP, 100 mg, 300 mg and 400 mg. The reference listed drug product to which you refer in your petition is Tegretol® (Carbamazepine) Tablets, 200 mg, approved under NDA 16-608 held by Novartis Pharmaceuticals Corporation.

Your request involves a change in strength from that of the listed drug product, i.e., from 200 mg tablets to 100 mg, 300 mg and 400 mg tablets. The change you request is the type of change that is authorized under the Federal Food, Drug, and Cosmetic Act (Act).

We have reviewed your petition under Section 505(j)(2)(C) of the Act and have determined that it is approved. This letter represents the Food and Drug Administration's (FDA) determination that an ANDA may be submitted for the above-referenced drug product.

Under Section 505(j)(2)(C)(i) of the Act, the FDA must approve a petition seeking strengths that differ from the strength of the listed drug product unless it finds that investigations must be conducted to show the safety and effectiveness of the differing strengths.

The FDA finds that the change in strengths for the specific proposed drug products does not pose questions of safety or effectiveness because the uses and route of administration of the proposed drug products are the same as that of the listed drug product. The FDA concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug products can be expected to have the same therapeutic effect as the listed reference drug product.

The approval of this petition to allow an ANDA to be submitted for the above-referenced drug products does not mean that the FDA has determined that an ANDA will be approved for the drug products. The determination of whether an ANDA will be approved is not made until the ANDA itself is submitted and reviewed by the FDA.

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Taro Pharmaceuticals U.S.A., Inc.
Carbamazepine Tablets USP, 100 mg, 300 mg, and 400 mg

To permit review of your ANDA submission, you must submit all information required under Sections 505(j)(2)(A) and (B) of the Act. To be approved, the drug products will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. For your information, requests for waivers of *in vivo* bioequivalence are not evaluated as part of the petition process. Requests for waivers are evaluated when the ANDA is submitted. We suggest that you submit your protocol for this drug product to the Office of Generic Drugs, Division of Bioequivalence, prior to the submission of your ANDA. During the review of your application, the FDA may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the one upon which you based this petition. In addition, you should refer in your ANDA to the appropriate petition docket number cited above, and include a copy of this letter in the ANDA submission.

A copy of this letter approving 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 yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research