



JUN 07 2006

Food and Drug Administration
Rockville MD 20857

DLA Piper Rudnick Gray Cary US LLP
Attention: David Rosen
1200 Nineteenth Street, NW
Washington, DC 20036-2412

Docket No. 2005P-0066/CP1

Dear Mr. Rosen:

This is in response to your petition filed on February 14, 2005, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Amlodipine Besylate Capsules, 2.5 mg, 5 mg and 10 mg. The listed drug product to which you refer in your petition is Norvasc (amlodipine besylate) Tablets, 2.5 mg, 5 mg and 10 mg, approved under NDA 19-787, held by Pfizer.

Your request involves a change in dosage form (i.e., from tablets to capsules) from that of the listed drug product. The change that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) and (ii) of the Act, such a petition will be approved unless the Agency finds that investigations must be conducted to show the safety and effectiveness of the proposed drug product, or of any of the active ingredients, the route of administration, the dosage form, or strength which differ from the listed drug product; or that any drug with a different active ingredient may not be adequately evaluated for approval as safe and effective on the basis of the information required to be submitted in an abbreviated application.

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 assess safety and effectiveness of the drug or biological product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration in each pediatric subpopulation in which the drug or biologic is safe and effective, unless the requirement is waived. 21 U.S.C. 355c. If a change proposed in a suitability petition triggers the need for pediatric clinical studies under PREA and those studies are not waived, the proposed product will not be eligible to be approved in an ANDA and the suitability petition must be denied.

Because you are seeking a change in dosage form, this proposed drug product triggers PREA. The Agency has determined that under PREA pediatric clinical trials are required. Although the NDA holder for Norvasc conducted pediatric studies and was awarded pediatric exclusivity, the Agency disagrees with your contention that the PREA requirement for pediatric studies should be waived. We have determined that, for adequate study of the pediatric population, additional information is required for pediatric subjects less than 6 years old.

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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 requirement under PREA has been denied. Please contact the Division of Cardio-Renal Drug Products at 301-594-5300 if you wish to pursue approval of your product under Section 505(b) of the Act.

If you disagree with our determination concerning the acceptability 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 Section 10.20, in the format outlined in Section 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 yours,



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