



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

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APR 18 2000

Andrx Pharmaceuticals, Inc.
Attention: Diane Servello
4001 S.W. 47th Ave.
Ft. Lauderdale, FL 33314

Docket No. 99P-1087/CP1

Dear Ms. Servello:

This is in response to your petition filed on April 23, 1999, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Omeprazole Delayed-release Tablets, 40 mg. The listed drug product to which you refer in your petition is Prilosec® (Omeprazole) Delayed-release Capsules, 40 mg manufactured by Astra Merck, Inc.

Your request involves a change in dosage form from that of the listed drug product (i.e., from delayed-release capsule to delayed release tablet). The change you request is the type of change that is authorized under the Act.

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

In addition, this petition was evaluated with respect to the Regulations Requiring Manufacturers to Assess the Safety and Effectiveness of New Drugs and Biological Products in Pediatric Patients; Final Rule, published in the Federal Register (Pediatric Rule)(63 FR 66632). The agency has determined that your proposed change in dosage form is subject to the Pediatric Rule, but has concluded that investigations are not necessary to demonstrate the safety and effectiveness of your proposed product in the pediatric population, because the Agency currently believes that this specific drug product does not represent a meaningful therapeutic benefit over existing therapies for pediatric patients and this dose is not likely to be used in a substantial number of pediatric patients. Accordingly, the pediatric study requirement is waived at this time but may be reevaluated if new information is available at the time you file your application.

The Agency concludes, therefore, that investigations are not necessary in this instance. In addition, if shown to meet bioavailability requirements, the proposed drug product can be expected to have the same therapeutic effect as the listed reference drug product.

99P-1087

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

For your information, the listed drug product to which you refer is covered by periods of patent protection and exclusivity which appear in the Approved Drug Products With Therapeutic Equivalence Evaluations, 19th Edition, published by the Agency. The existence of such patents and exclusivity will require a patent certification and exclusivity statement upon submission of an ANDA for your proposed drug product and may also affect the approval date of any ANDA.

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 product will, among other things, be required to meet current bioavailability requirements under Section 505(j)(2)(A)(iv) of the Act. We suggest that you submit your protocol to the Office of Generic Drugs, Division of Bioequivalence prior to the submission of your ANDA. During the review of your application, the Agency may require the submission of additional information.

The listed drug product to which you refer in your ANDA must be the drug product 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
Acting Director
Office of Generic Drugs
Center for Drug Evaluation and Research