



Food and Drug Administration
Rockville MD 20857

NDA 20-916

Astra Merck
Attention: Gary P. Horowitz, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Horowitz :

Please refer to your new drug application dated September 30, 1997, received September 30, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRILOSEC (omeprazole) Delayed-Release Capsules.

We acknowledge receipt of your submissions dated November 7 and December 5, 1997, February 4, March 9, April 3, 9, 22, May 21, June 4, 16, 17, 25 and 29, 1998. The User Fee goal date for this application is September 30, 1998.

This new drug application provides for the concomitant use of PRILOSEC Delayed-Release Capsules, amoxicillin and clarithromycin for the eradication of *H. pylori* in patients with duodenal ulcer disease.

We have completed the review of this application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the draft labeling in the submission dated June 29, 1998. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling submitted on June 29, 1998. Marketing the product with FPL that is not identical to this draft labeling may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FINAL PRINTED LABELING" for approved NDA 20-916. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional material that you

propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Robin Anderson, Project Manager, at (301) 827-2127.

Sincerely yours,

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogens and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research