June 4, 1998

NDA 20-838

Astra Merck Inc.
Attention: Daniel J. Cushing, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Cushing:

Please refer to your April 30, 1997 new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Atacand (candesartan cilexetil) 4, 8, 16, and 32 mg Tablets.

We acknowledge receipt of your submissions dated April 28, May 6, 8, 12, 18, 20 and 22(two), 1998.

This new drug application provides for the use of Atacand (candesartan) Tablets in the treatment of hypertension.

We have completed the review of this application and have concluded that adequate information has been presented to demonstrate that the drug is safe and effective for use as recommended in the final printed package insert included with your May 18, 1998 submission. Accordingly, the application is approved effective on the date of this letter.

We note that one of the May 22, 1998 submissions contains camera-ready proofs of carton and container labeling. Please submit 20 copies of the final printed carton and container labels as soon as they are available, in no case more than 30 days after they are 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 20-838. Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

We note that the tentative dissolution specifications will be:

and you will monitor the dissolution of the first three batches of the 16 and 32 mg tablets placed on stability testing with the aim of revising the specifications for these strengths to Q
45 minutes.

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

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

If you have any questions, please contact:

Ms. Kathleen Bongiovanni
Regulatory Health Project Manager
(301) 594-5334

Sincerely yours,

Robert Temple, M.D.
Director
Office of Drug Evaluation I
Center for Drug Evaluation and Research