DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

NDA 20-850

NOV 10 1998

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Ms. Heidi Reidies
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Ms. Reidies:

Please refer to your new drug application (NDA) dated September 26, 1997, received September 26, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Micardis (telmisartan) 40 and 80 mg Tablets.

We acknowledge receipt of your submissions dated October 6, 15 and 23 and November 3, 1998.

This new drug application provides for the use of Micardis (telmisartan) 40 and 80 mg Tablets for the treatment of hypertension.

We have completed the review of this application, as amended, 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 submitted final printed labeling (package insert included in the November 3, 1998 submission, blisters included in the October 23, 1998 submission, and carton labels included in the October 15, 1998 submission). Accordingly, the application is approved effective on the date of this letter.

We remind you of your Phase 4 commitments specified in your submission dated October 23, 1998. These commitments, along with any completion dates agreed upon, are listed below.

Under 21 CFR 314.82(b)(2)(vii), we request that you include a status summary of each commitment in your annual report to this NDA. The status summary should include expected completion and submission dates, and any changes in plans since the last annual report. For administrative purposes, all submissions, including supplements, relating to these Phase 4 commitments must be clearly designated "Phase 4 Commitments."

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.

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:

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