

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 20850

APPROVAL LETTER

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.

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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**

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 20850

APPROVABLE LETTER



Food and Drug Administration
Rockville MD 20857

NDA 20-850

SEP 25 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, 21, 28, 29 and 30, November 3, 6, 7 (two), 18 and 25 and December 9, 12, 16, 18 and 23, 1997; January 9, 28 and 30, February 5, 6 and 17, March 3, April 17, 24 and 29, May 8, 15, 19 and 22, June 4, 8 (two), 10, 17, 19, 23 and 26, July 10 and 15, August 18 and September 10, 11 and 17, 1998.

The user fee goal date for this application is September 26, 1998.

We have completed the review of this application, as amended, and it is approvable. Before this application may be approved, however, it will be necessary for you to submit final printed labeling (FPL) for the drug. The labeling should be identical in content to the enclosed draft package insert, draft cartons and blisters included in your July 15, 1998 submission, and draft professional sample cartons for 80 mg included in your September 10, 1998 submission.

We also note that the lowest dose of telmisartan that can be given patients (40 mg) is close to the dose giving the maximum effect on blood pressure and that this dose gives higher blood levels than usual in women and patients with hepatic or renal dysfunction. Although this had no observed consequences in the patients studied, the available doses do not permit use of a reduced dose in people with volume or salt depletion. This will be noted in the labeling for the present, but we ask for your assurance that a lower dosage strength tablet be developed promptly. Please submit a description of information that will be submitted to support the lower dosage strength tablet, along with a proposed timeline.

We note that you have agreed to revise the statement on your carton at the time of the next printing from:

Please describe this change in your next annual report, as provided for under 21 CFR 314.70(d)(3), an editorial or similar minor change in labeling.

Please submit 20 copies of the final printed labeling, ten of which are individually mounted on heavy weight paper or similar material.

In addition, please change the dissolution specification to "Q of % in minutes."

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Cardio-Renal Drug Products and two copies of both the promotional materials and the package insert directly to:

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

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

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

Enclosure