



NDA 20-850/S-005

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Ms. Kelly Billingham
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated January 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MICARDIS (telmisartan) 20, 40 and 80 mg Tablets.

We acknowledge receipt of your submissions dated June 20, 2002, and May 22 and August 25, 2003. Your submission of August 25, 2003 constituted a complete response to our June 19, 2002 approvable letter.

This "Changes Being Effected" supplemental new drug application provides for final electronic printed labeling revised as follows:

1. Above the **DESCRIPTION** section, the phrase "**Prescribing Information**" has been added.
2. Under the **DESCRIPTION** section, the first sentence of the second paragraph has been changed to "Telmisartan is a white or slightly yellow crystalline substance."
3. Under **WARNINGS, Fetal/Neonatal Morbidity and Mortality**, 7th paragraph, 3rd line, "[about 6.4 times...]" has been changed to "[about 12 times...]."
4. Under **PRECAUTIONS, Drug Interactions, Other Drugs**, the drug "simvastatin" was added to the 1st sentence of this subsection.
5. Under **ADVERSE REACTIONS**, the last sentence of this section that read "A single case of angioedema was reported (among a total of 3781 patients treated with telmisartan)" has been changed to:

During initial clinical studies, a single case of angioedema was reported (among a total of 3781 patients treated). In post-marketing experience, additional cases of angioedema and urticaria have been noted.

6. Under **HOW SUPPLIED**, the phrase "Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F)" has been placed in bold print. In addition, the parentheses surrounding "see USP Controlled Room Temperature" have been replaced with brackets.

We have completed the review of this supplemental application 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 electronic printed labeling (package insert included in your submission of August 25, 2003). Accordingly, the supplemental application is approved effective on the date of this letter.

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:

Mr. Edward Fromm
Regulatory Health Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Doug Throckmorton
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