



NDA 21-162/S-008

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

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated 24 February 2005, received 28 February 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MICARDIS HCT (telmisartan/hydrochlorothiazide) 40 mg/ 12.5 mg, 80 mg/ 12.5 mg, and 80 mg/ 25 mg Tablets.

We also refer to your submission dated 25 August 2005.

This “Changes Being Effectuated” supplemental new drug application provides for the following revisions:

1. Under the **ADVERSE REACTIONS:** Telmisartan section, the following revisions are noted:

- Deleted text:
“(b) (4) _____”
- The following new sub-section was added:

Post-Marketing Experience

The following adverse reactions have been identified during post-approval use of MICARDIS tablets. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or establish a causal relationship to drug exposure. Decisions to include these reactions in labeling are typically based on one or more of the following factors: (1) seriousness of the reaction, (2) frequency of reporting, or (3) strength of causal connection to MICARDIS tablets. The most frequently spontaneously reported events include: headache, dizziness, asthenia, coughing, nausea, fatigue, weakness, edema, face edema, lower limb edema, angioneurotic edema, urticaria, hypersensitivity, sweating increased, erythema, chest pain, atrial fibrillation, congestive heart failure, myocardial infarction, blood pressure increased, hypertension aggravated, hypotension (including postural hypotension), hyperkalemia, syncope, dyspepsia, diarrhea, pain, urinary tract infection, erectile dysfunction, back pain, abdominal pain, muscle cramps (including leg cramps), and myalgia.

Rare cases of rhabdomyolysis have been reported in patients receiving angiotensin II receptor blockers, including MICARDIS.

2. Under the **HOW SUPPLIED**, revisions were made to reflect the following:

- 30-count configuration for all 3 strengths (30 tablets as 3 X 10 cards) was added and information referring to the 28-count (28 tablets as 4 X 7 cards) was deleted.

- The NDC numbers were added for the new 30-count configurations
- MICARDIS HCT Tablets 40 mg/12.5 mg, **NDC 0597-0043-37**
- MICARDIS HCT Tablets 80 mg/12.5 mg, **NDC 0597-0044-37**
- MICARDIS HCT Tablets 80 mg/ 25 mg, **NDC 0597-0042-37**

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the electronic agreed-upon labeling text.

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 call:

Cheryl Ann Borden, MSN, RN, CCRN, CCNS
Regulatory Health Project Manager
(301) 594 5312.

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Norman Stockbridge
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