DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-850/S-013

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® (telmisartan) 20, 40, and 80 mg Tablets.

We also refer to your submission dated 25 August 2005.

This supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY**, **Special Populations**, *Renal Insufficiency* section, the **ADVERSE REACTIONS, Post-Marketing Experience** subsection, and the **DOSAGE AND ADMINISTRATION** Section.

1. Revisions to the **CLINICAL PHARMACOLOGY, Special Populations**, *Renal Insufficiency* section are as follows:

   From:

   Renal Insufficiency: Renal excretion does not contribute to the clearance of telmisartan. Based on modest experience in patients with mild to moderate renal impairment (creatinine clearance of 30-80 mL/min, mean clearance approximately 50 mL/min), no dosage adjustment is necessary in patients with decreased renal function. Telmisartan is not removed from blood by hemofiltration (see **PRECAUTIONS, and DOSAGE AND ADMINISTRATION**).

   To:

   No dosage adjustment is necessary in patients with decreased renal function. Telmisartan is not removed from blood by hemofiltration (see PRECAUTIONS, and DOSAGE AND ADMINISTRATION).

2. Under **ADVERSE EVENTS** the following **Post-Marketing Experience** sub-section was added:

   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.

3. The **DOSAGE AND ADMINISTRATION** section, the 5th paragraph has been revised as follows:

   From:

   No initial dosing adjustment is necessary for elderly patients or patients with mild to moderate renal impairment. Patients on dialysis may develop orthostatic hypotension; their blood pressure should be closely monitored.

   To:

   No initial dosing adjustment is necessary for elderly patients or patients with renal impairment, including those on hemodialysis. Patients on dialysis may develop orthostatic hypotension; their blood pressure should be monitored closely.

4. Minor administrative changes were noted to the Copyright and the Revised date to reflect updated label date of 2005.

We completed our review of this supplemental new drug application, as amended. 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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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