DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020850/S-031

SUPPLEMENT APPROVAL

Boehringer Ingelheim
Attention: Nathan Chen
Associate Director, Drug Regulatory Affairs
900 Ridgebury Road, PO Box 368
Ridgefield, CT 06877

Dear Mr. Chen:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 28, 2011, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Micardis (telmisartan) 20 mg, 40 mg, and 80 mg Tablets.

We also acknowledge receipt of your amendment dated October 19, 2011.

This "Prior Approval" supplemental new drug application provides for labeling revised as follows:

1. In **HIGHLIGHTS/RECENT MAJOR CHANGES**, the following was added:

   Contraindications (4) 1/2011

2. In **HIGHLIGHTS/RECENT MAJOR CHANGES**, the following was deleted:

   Indications and Usage, Cardiovascular Risk Reduction (1.2) 10/2009
   Dosage and Administration, Cardiovascular Risk Reduction (2.2) 10/2009
   Warnings and Precautions,
   Dual Blockade of the Renin-Angiotensin-Aldosterone System (5.6) 9/2009

3. In **HIGHLIGHTS/CONTRAINDICATIONS**, the following bullet was added:

   - Known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product (4)

4. Under **CONTRAINDICATIONS**, the following text was added as the first paragraph:

   MICARDIS is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis or angioedema) to telmisartan or any other component of this product *[see Adverse Reactions (6.2)]*.

5. Under **ADVERSE REACTIONS/Post-Marketing Experience/*Telmisartan***, the first paragraph was changed from:

The most frequent 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), myalgia, bradycardia, eosinophilia, thrombocytopenia, uric acid increased, abnormal hepatic function/liver disorder, renal impairment including acute renal failure, anemia, and increased CPK, anaphylactic reaction, and tendon pain (including tendonitis, tenosynovitis).

To:

The most frequent 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), myalgia, bradycardia, eosinophilia, thrombocytopenia, uric acid increased, abnormal hepatic function/liver disorder, renal impairment including acute renal failure, anemia, and increased CPK, anaphylactic reaction, tendon pain (including tendonitis, tenosynovitis), drug eruption (e.g. toxic skin eruption mostly reported as toxicoderma, rash, and urticaria), hypoglycemia (in diabetic patients), and angioedema (with fatal outcome).

6. Under **USE IN SPECIFIC POPULATIONS/Pediatric Use**, a reference has been added. The section now reads:

8.4 Pediatric Use
Safety and effectiveness in pediatric patients have not been established *[see Clinical Pharmacology (12.3)]*.

7. Under **PATIENT COUNSELING INFORMATION**, the statement was changed from:

See FDA-Approved Patient Labeling(17.2).

To:

See FDA-Approved Patient Labeling.

8. Under **PATIENT COUNSELING INFORMATION**, the following heading was changed from:

17.2 FDA-Approved Patient Labeling

To:

FDA-Approved Patient Labeling

9. Under **Patient Information**, a new section was added:

   Who should not take MICARDIS?

   You should not take MICARDIS tablets if you are allergic (hypersensitive) to the active ingredient (telmisartan) or any of the other ingredients listed at the end of this leaflet.

10. Under **Patient Information/What are the possible side effects of MICARDIS tablets?**, an additional bullet was added:

    - skin rash

11. It is noted that there are numerous editorial changes, too numerous to mention, throughout the label.

12. The revision date and version number were updated.

There are no other changes from the last approved package insert.

We have completed our review of this supplemental application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call:

Lori Anne Wachter, RN, BSN
Regulatory Project Manager for Safety
(301) 796-3975

Sincerely,

{See appended electronic signature page}

Mary Ross Southworth, Pharm.D.
Deputy Director for Safety
Division of Cardiovascular and Renal Products
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

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

/s/

MARY R SOUTHWORTH
01/18/2012