DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20-850/S-022/S-023

APPROVAL LETTER

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

Dear Ms. Billingham:

Please refer to your supplemental new drug applications dated September 24 (S-022) and September 25 (S-023), 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Micardis (telmisartan) 20 mg, 40 mg and 80 mg Tablets.

We acknowledge receipt of your submissions dated March 24, June 12 and July 9, 2009.

These supplemental new drug applications provide for revisions to the **PRECAUTIONS** and **ADVERSE REACTIONS** sections of the package insert.

We have completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

Within 14 days from the date of this letter, please amend any pending supplemental application, including "Changes Being Effected" supplements for which the labeling is in effect, but for which FDA has not yet issued an action letter, for this NDA with content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm that includes the changes approved in this application.

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
Food and Drug Administration
Suite 12B05
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:

Quynh Nguyen, PharmD, RAC
Regulatory Project Manager
(301) 796-0510

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 I
Center for Drug Evaluation and Research

Attachment:
agreed-upon labeling text

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
08/11/2009