



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-850/S-019

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

Dear Ms. Billingham:

Please refer to your supplemental new drug application dated June 9, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Micardis® (telmisartan) 20, 40 and 80 mg Tablets.

This "Changes Being Effected" supplemental new drug application provides for revisions to the **ADVERSE REACTIONS** and **HOW SUPPLIED** sections of the labeling.

This supplemental new drug application provides for electronic final printed labeling with the following revisions:

1. Under the **ADVERSE REACTIONS**, *Post Marketing Experience* subsection, the following events have been added:

bradycardia, eosinophilia, thrombocytopenia, uric acid increased, abnormal hepatic function/liver disorder, renal impairment including acute renal failure, anemia, and increased CPK.

2. Revisions to the **HOW SUPPLIED** section are as follows:

From:

MICARDIS (telmisartan) tablets 20 mg are round and individually blister-sealed in cartons of 28 tablets as 4 x 7 cards (NDA 0597-0039-28).

To:

MICARDIS (telmisartan) tablets 20 mg are round and individually blister-sealed in cartons of 30 tablets as 3 x 10 cards (NDC 0597-0039-37).

From:

Manufactured by:
Boehringer Ingelheim Pharma GmbH & Co. KG
Ingelheim, Germany

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Boehringer Ingelheim International GmbH,
Ingelheim, Germany

Marketed by:
Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA
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Abbott Laboratories, North Chicago, IL 60064 USA

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Revised 08/19/05
553206/US/x or 340194/US/x
OT1200

To:
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Ridgefield, CT 06877 USA

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Micardis Tablets are covered by U.S. Patent 5,591,762

Revised: May 25, 2006
OTI200B
340194/US/3
553206/US/11

We have completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the electronic labeling submitted on June 9, 2006.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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:

Quynh Nguyen, Pharm.D.
Regulatory Project Manager
(301) 796-0510

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Director
Division of Cardiovascular and Renal 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
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/s/

Norman Stockbridge
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