DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-162/S-016

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 HCT® (telmisartan/hydrochlorothiazide) 40/12.5, 80/12.5 and 80/25 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 to this section and have been moved to follow the *Hydrochlorothiazide* subsection:

   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:

Manufactured by:	Boehringer Ingelheim Pharma GmbH & Co. KG, Ingelheim, Germany
Marketed by:	Boehringer Ingelheim Pharmaceuticals, Inc., Ridgefield, CT 06877 USA and Abbott Laboratories, North Chicago, IL 60064 USA
Licensed from:	Boehringer Ingelheim International GmbH, Ingelheim, Germany

To:

Distributed by: Boehringer Ingelheim Pharmaceuticals, Inc.,
Ridgefield, CT 06877 USA

Licensed from: Boehringer Ingelheim International GmbH,
Ingelheim, Germany

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

Revised: June 2, 2006

IT1105A
340139/US/4
340139/04
10004142/US/2
10004142/02

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 this page is the manifestation of the electronic signature.

/s/

Norman Stockbridge

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