DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-938/S-017
NDA 21-530/S-005

CBE-0 SUPPLEMENT

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Attention: Martin M. Kaplan, M.D., J.D.
Vice President, Drug Regulatory Affairs

Dear Dr. Kaplan:

Please refer to your supplemental new drug applications dated July 13, 2006, received July 14, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA	Supplement	Drug Product
20-938	S-017	Mobic® (meloxicam) 7.5 and 15 mg Tablets
21-530	S-005	Mobic® (meloxicam) 7.5 mg/5 mL Oral Suspension

These "Changes Being Effected" supplemental new drug applications provide for:

1. An addition to the **WARNINGS: Renal Effects** section to identify patients taking angiontensin II receptor agonists while receiving NSAID therapy as also being at the greatest risk of renal injury.

2. An addition to **ADVERSE REACTIONS** section to include acute urinary retention and the term "Accident Household".

3. Incorporation of the NSAID class-labeling language in the **Medication Guide**.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling text for the package insert and for the Medication Guide.

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, call Kathleen Davies, Regulatory Project Manager, at (301) 796-2205.

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Director
Division of Anesthesia, Analgesia
and Rheumatology Products
Office of Drug Evaluation II
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/

Bob Rappaport

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