DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020938/S-020
NDA 021530/S-008

SUPPLEMENT APPROVAL

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

Attention: Kelly Billingham
Associate Director, Drug Regulatory Affairs

Dear Ms. Billingham:

Please refer to your Supplemental New Drug Applications (sNDA) dated May 14, 2010, received May 17, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Supplement	Drug Product
020938	S-020	Mobic (meloxicam) 7.5 and 15 mg Tablets
021530	S-008	Mobic (meloxicam) 7.5 mg/5 mL Oral Suspension

These “Prior Approval” supplemental new drug applications provide for the following revisions:

1. Highlights: Since the contraindication for "known hypersensitivity" is retained in section 4, the Highlights have been updated accordingly in the attached labeling.

2. Section 5.6, Renal Effects: revising the "subjects" to “patients” in the second sentence of the second paragraph.

3. Section 6, Adverse Reactions: the bulleted list of adverse reactions is consistent with the corresponding sub-headers in section 5.

4. Cross references have been corrected throughout to reflect the re-ordering of the Warnings and Precautions section.

We have completed our review of these supplemental applications. They are 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, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling (text for the package insert, Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. 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 pending "Changes Being Effected" (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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA, to CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
Director
Division of Anesthesia and Analgesia Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling
Medication Guide

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21530	SUPPL-8	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	MOBIC (MELOXICAM) ORAL SUSP 7.5MG/5ML
NDA-20938	SUPPL-20	BOEHRINGER INGELHEIM PHARMACEUTICALS INC	MOBIC

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/s/

BOB A RAPPAPORT
07/29/2010