DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020938/S-021
NDA 021530/S-009

NDA APPROVAL

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

Attention: Huiping Jiang, Ph.D.
Associate Director, Drug Regulatory Affairs

Dear Dr. Jiang:

Please refer to your supplemental new drug applications dated January 19, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA	Supplement	Receipt Date	Drug Product
020938	S-021	January 20, 2011	Mobic® (meloxicam) 7.5 and 15 mg Tablets
021530	S-009	January 19, 2011	Mobic® (meloxicam) 7.5 mg/5 mL Oral Suspension

We also refer to our approval letter dated August 3, 2011, which contained the following error: error in final agreed-upon labeling attached to the letter.

This replacement approval letter incorporates the correction of the error. The effective approval date will remain August 3, 2011, the date of the original approval letter.

We also refer to your submission dated June 10, 2011.

These Prior Approval supplemental new drug applications propose the following changes:

1. Highlights: updated the Drug Interactions section to include a statement about the risk of colonic necrosis when Mobic oral suspension is administered concomitantly with sodium polystyrene.

2. Section 7: updated to include a new section 7.8 to include information on intestinal necrosis in patients who received concomitant sorbitol and sodium polystyrene sulfonate.

We have completed our review of these supplemental applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text submitted January 19 and June 10, 2011.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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, Senior Regulatory Project Manager, at (301) 796-2205.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE (1):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

BOB A RAPPAPORT
08/03/2011