DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-938/S-013, S-015
NDA 21-530/S-001, S-003

Boehringer Ingelheim Pharmaceuticals, Inc.
900 Ridgebury Road/P.O. Box 368
Ridgefield, CT 06877-0368

Attention: Charles R. Mazzarella
Associate Director, Drug Regulatory Affairs

Dear Mr. Mazzarella:

Please refer to your supplemental new drug applications dated February 18, 2005, received February 18, 2005 (NDA 20-938/S-013 and NDA 21-530/S-001), and dated July 14, 2005, received July 15, 2005 (NDA 20-938/S-015 and NDA 21-530/S-003), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mobic® (meloxicam) Tablets and Mobic® (meloxicam) Oral Suspension.

We acknowledge receipt of your submissions dated April 11, May 2 and 18, June 10, 16, 17, and 27, July 21, and August 10, 2005 (NDA 20-938/S-013 and NDA 21-530/S-001), and your submission dated August 5, 2005, (NDA 20-938/S-015 and NDA 21-530/S-003.)

Supplements S-013 (N 20-938) and S-001 (N 21-530) provide for the use of Mobic® (meloxicam) Tablets and Mobic Oral Suspension for relief of the signs and symptoms of pauciarticular or polyarticular course Juvenile Rheumatoid Arthritis in patients 2 years of age and older.

Supplements S-015 (N 20-938) and S-003 (N 21-530) provide for the revised package insert to include a boxed warning, additional information about cardiovascular risks, and a MedGuide as requested by the Agency in the June 14, 2005, letter.

We have completed our review of these applications, as amended, 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 package insert and MedGuide submitted August 10, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA.* Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions "**FPL for approved supplements NDA 20-938/S-013, S-015 and NDA 21-530/S-001, S-003**." Approval of these submissions by the FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anesthesia, Analgesia and Rheumatology Products and two copies of both the promotional materials and the package inserts directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Effective August 29, 2005, **ALL** regulatory submissions, whether sent by U.S. Postal Service, an overnight mail service, or courier, should be sent to the following address. Processing of submissions sent to other addresses may be delayed.

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Anesthesia, Analgesia and Rheumatology Products
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Constantine J. Markos, Pharm.D., Regulatory Health Project Manager, at (301) 827-2496.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Sharon Hertz
8/11/05 03:20:43 PM
Signing for Bob Rappaport, MD