NDA 20-938

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Martin M. Kaplan, M.D., J.D.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Dr. Kaplan:

Please refer to your new drug application (NDA) dated December 15, 1998, received December 16, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mobic**7** (meloxicam) Tablets 7.5 mg.

We acknowledge receipt of your submissions dated January 31, February 11, and February 28, March 27, April 3, April 10, and April 13, 2000. Your submission of February 11, 2000 constituted a complete response to our December 15, 1999 action letter.

This new drug application provides for the use of Mobic**7** (meloxicam) Tablets 7.5 mg for relief of the signs and symptoms of osteoarthritis.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved NDA 20-938." Approval of this submission by FDA is not required before the labeling is used.
In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Anthony M. Zeccola, Senior Regulatory Management Officer, at (301) 827-2090.

Sincerely,

Robert DeLap, M.D., Ph.D.
Director
Office of Drug Evaluation V
Center for Drug Evaluation and Research