



NDA 20-938/S-004

Boehringer Ingelheim Pharmaceuticals, Inc.  
Attention: Jeffery R. Snyder  
Senior Associate Director  
Drug Regulatory Affairs  
900 Ridgebury, Road  
Ridgefield, CT 06877

Dear Mr. Snyder:

Please refer to your supplemental new drug application dated February 28, 2001, received February 28, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mobic® (meloxicam) Tablets, 7.5 mg and 15 mg.

We acknowledge receipt of your submissions dated December 20, 2001; January 18, and February 05, 2002; January 15, February 10, and 26, May 26, and June 18, 2004. Your submission of January 15, 2004 constituted a complete response to our December 21, 2001 action letter.

This supplemental new drug application provides for the use of Mobic® (meloxicam) Tablets, 7.5 mg and 15 mg for the relief of the signs and symptoms of rheumatoid arthritis in adults.

We completed our review of this application, as amended. This application is 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.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper.

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 are waiving the pediatric study requirement for ages 0 to < 2 years and deferring pediatric studies for ages 2 years to 17 years for this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of juvenile rheumatoid arthritis in pediatric patients ages 2 years to 17 years.

Final Report Submission: January 31, 2005

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated “**Required Pediatric Study Commitments**”.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Anti-Inflammatory, Analgesic, & Ophthalmic Drug Products and two copies of both the promotional materials and the package insert 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

Please submit one market package of the drug product when it is available. 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 Barbara Gould, Regulatory Project Manager, at (301) 827-2506.

Sincerely,

*{See appended electronic signature page}*

Brian E. Harvey, M.D., Ph.D.  
Acting Director  
Division of Anti-Inflammatory, Analgesic, &  
Ophthalmic Drug Products  
Office of Drug Evaluation V  
Center for Drug Evaluation and Research

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Brian Harvey

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