



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-938/S-007

Boehringer Ingelheim Pharmaceuticals, Inc.
Attention: Tacy Pack
Senior Associate Director,
Drug Regulatory Affairs Product Labeling
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877-0368

Dear Ms. Pack:

Please refer to your supplemental new drug application, dated February 26, 2002, received February 27, 2002, 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 submission dated February 19, 2003.

This "Supplemental Labeling Revision-Changes Being Effected" supplemental new drug application provides for final printed labeling (FPL) with changes to the DESCRIPTION, PRECAUTIONS, DOSAGE AND ADMINISTRATION, AND HOW SUPPLIED sections of the package insert. Also, your amendment provides for deletion of the phrase b(4)----- from the product storage statement and revision of the name of the manufacturing site in Germany.

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.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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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 Stacey N. Welch, Regulatory Health Project Manager, at 301-827-2496.

Sincerely,

{See appended electronic signature page.}

Lee S. Simon, M.D.

Director

Division of Anti-inflammatory, Analgesic,
and Ophthalmic Drug Products, HFD-550

Office of Drug Evaluation V

Center for Drug Evaluation and Research

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

/s/

Lee Simon

4/28/03 06:29:18 PM