



NDA 20-938/S-018

NDA 21-530/S-006

CBE-0 SUPPLEMENT

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

Attention: Martin M. Kaplan, M.D., J.D.
Vice President, Drug Regulatory Affairs

Dear Dr. Kaplan:

Please refer to your supplemental new drug applications dated April 15, 2008, received April 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA	Supplement	Drug Product
20-938	S-018	Mobic® (meloxicam) 7.5 and 15 mg Tablets
21-530	S-006	Mobic® (meloxicam) 7.5 mg/5 mL Oral Suspension

These “Changes Being Effected” supplemental new drug applications provide for revisions to the **ADVERSE REACTIONS** section to include the term “alterations in mood (such as mood elevation)” to the list of post-marketing adverse drug reactions. In addition, the statement “and are considered rare (< 0.1%)” in the post-marketing experience section is deleted.

We have completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the enclosed content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on April 15, 2008. We will transmit this version to the National Library of Medicine for public dissemination.

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD

Director

Division of Anesthesia, Analgesia
and Rheumatology Products

Office of Drug Evaluation II

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/

Bob Rappaport
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