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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

NDA 21-530

Approval Letter(s)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-530

Boehringer Ingelheim Pharmaceutical, Inc.
Attention: Charles Mazzearella
Manager, Drug Regulatory Affairs
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

Dear Mr. Mazzearella:

Please refer to your new drug application (NDA) dated August 18, 2003, received August 19, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mobic® Oral Suspension (meloxicam oral suspension), 7.5 mg/5 mL.

We acknowledge receipt of your submissions dated October 29, and December 18, 2003; and January 21, February 13, and 25, March 12, April 13, 26, and 28, and May 10, 12, and 18, 2004.

This new drug application provides for the use of Mobic® Oral Suspension (meloxicam oral suspension) 7.5 mg/5 mL for the relief of the signs and symptoms of osteoarthritis.

We completed our review of this application, as amended. It 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 (text for the package insert) and submitted labeling package insert submitted May 10, 2004, and the (immediate container and carton labels submitted August 18, 2003). Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 this submission "**FPL for approved NDA 21-530.**" Approval of this submission by 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 are waiving the pediatric study requirement for this application.

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, and 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

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

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

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

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

Brian Harvey

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