



NDA 19-645/S-018

Hoffmann-La Roche Inc.
340 Kingsland Street
Nutley, NJ 07110-1199

Attention: Lynn DeVenezia-Tobias
Senior Program Manager, Diversified Products

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated June 30, 2008, received July 2, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toradol® Oral (ketorolac tromethamine) 10 mg tablets.

This “Changes Being Effected” supplemental new drug application provides for changes to the Medication Guide as requested in the January 3, 2008 Federal Register.

We have completed our review of this supplemental new drug application and it is 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 printed labeling (SPL) submitted on June 30, 2008, and with the following editorial revision to the Medication Guide as agreed upon in an email exchange with Ms. DeVenezia-Tobias on December 5, 2008:

“Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.”

We will transmit the content of labeling in SPL format, as amended, 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Jessica Benjamin, Regulatory Project Manager, at (301) 796-3924.

Sincerely,

{See appended electronic signature page}

Bob A. Rappaport, M.D.
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
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/s/

Sharon Hertz
12/16/2008 02:43:22 PM
Signing for Bob Rappaport, M.D.