DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-645/S-017

Roche Palo Alto LLC
(c/o) Hoffmann-La Roche Inc.
340 Kingland Street
Nutley, NJ 07110-1199

Attention: Lynn DeVenezia-Tobias
Program Manager

Dear Ms. DeVenezia-Tobias:

Please refer to your supplemental new drug application dated June 12, 2007, received June 13, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Toradol® (ketorolac tromethamine) Tablets.

This supplemental new drug application provides for new information in the WARNINGS, PRECAUTIONS, ADVERSE REACTIONS and OVERDOSAGE sections of the package insert.

We have completed our review of this application. 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 product labeling (SPL) format (submitted on June 12, 2007). 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

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

Sincerely,

{See appended electronic signature page}

Bob Rappaport, MD
Division 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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