



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-628/S-068

NDA 18-084/S-052

Ortho McNeil Pharmaceuticals, Inc.
c/o Johnson & Johnson Pharmaceutical Research & Development, LLC
1125 Trenton-Harbourton Rd
Titusville, NJ 08560-0200

Attention: Kathleen F. Dusek, R.Ph., RAC
Associate Director, Regulatory Affairs

Dear Ms. Dusek:

Please refer to your supplemental new drug applications dated March 29, 2007, received March 29, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Tolectin DS (tolmetin sodium) capsules and Tolectin 600 (tolmetin sodium) tablets.

We acknowledge receipt of your submissions dated September 11, October 3, and December 4, 2007.

These “Changes Being Effected” supplemental new drug applications provide for updates to the NSAID Medication Guide as requested in our Supplement Request letter of January 5, 2007.

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 December 4, 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Kimberly Compton, Regulatory Health Project Manager, at (301) 796-1191.

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

Enclosure

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

/s/

Sharon Hertz

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