



NDA 20-204/S-021

Bayer Healthcare
Consumer Care Division
Attention: Barbara C. Cifelli
Manager, Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, New Jersey 07962-1910

Dear Ms. Cifelli:

Please refer to your supplemental new drug application dated November 5, 2004, received November 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Midol Extended Relief (220 mg naproxen sodium) tablets.

This supplemental new drug application provides for revised Drug Facts labeling including changes in the text of the Directions section and a re-ordering of age groups.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on November 5, 2004 for the immediate container and carton labels for the 24 count package.

The Agency is concerned about the need for organ-specific warnings and cardiovascular information for OTC drug products containing analgesic/antipyretic active ingredients. We will provide guidance on wording and placement of this information in the labeling of drug products containing NSAID's in the future.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of New Drugs
Center for Drug Evaluation and Research

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/s/

Curtis Rosebraugh
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