DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 20-204/S008

Bayer-Consumer Care Division
Attn: MaryRose Salvacion
Manager Regulatory Affairs
36 Columbia Road
P.O.Box 1910
Morristown, New Jersey 07962-1910

Dear Ms. Salvacion:

Please refer to your supplemental new drug application dated December 23, 1998, received on December 28, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve (naproxen sodium) tablets. We also acknowledge receipt of your submissions dated June 17, 1999, and January 24, and August 17, 2000, and March 7, 2001.

This supplemental application provides for a product line extension (additional tradename) for Maximum Strength Midol (naproxen sodium, 220 mg) tablets.

We have completed the review of this supplemental new drug application, as amended, it is approved effective on the date of this letter. You are reminded that this approval applies to the 24 caplet package only. You will need to submit a "Changes Being Effected" Supplement prior to incorporating this proposed change on your other package sizes.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-204/S-008." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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

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 Walter J. Ellenberg, Ph.D., Regulatory Health Project Manager, at 301-827-2279.

Sincerely,

{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Division Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

#8124 - MIDOL
PHASE 6 - 1/26/01
CARTON FLAT COLOR - TYPE CHANGES

RULES
THICK RULES 2.5 PT.
THIN RULES .5 PT.

LE
TITLE 9 PT. BOLD
HEADINGS 8 PT. BOLD
SUB HEADINGS 6 PT
TEXT 6 P
6.5 PT. LE
BULLETED STATEMENTS 6 P
BULLETS 5 P
DRUG FACTS (continued) 8 P

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

/s/

Linda Katz

3/19/02 04:45:14 PM