



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

Midol
MAXIMUM STRENGTH
ALL DAY FORMULA

USE ONLY IF BUSTER UNIT IS UNBROKEN

NEW INGREDIENT!

MAXIMUM STRENGTH

Midol

naproxen sodium tablets, 220 mg
Pain reliever

UP TO 12 HOUR RELIEF OF:

- Menstrual Cramps
- Muscle Aches
- Headaches
- Backaches

EXTENDED RELIEF

24 CAPLETS*

**capsule-shaped tablets*

Midol

Distributed by: Bayer Corporation
 Consumer Care Division
 Morris Plains, NJ 07960 USA B-R-LLC

LOT & EXP AREA

EXPIRES

Drug Facts (continued)

Other information: Each caplet contains: sodium 20 mg • Store at 20-25°C (68-77°F) • Avoid high humidity and excessive heat (104°F (40°C))

Inactive ingredients: magnesium stearate, microcrystalline cellulose, opadry YS-1-7002, povidone, talc.

Questions or comments? call 1-800-395-0689

Drug Facts

Active ingredient (in each caplet)
 Naproxen sodium 220 mg (naproxen 200 mg)
Pain reliever

Uses: Temporarily relieves minor aches and pains due to: • menstrual cramps • muscle aches • headache • backache

Warnings:
 Allergy alert: naproxen sodium may cause a severe allergic reaction which may include • hives • facial swelling • asthma (wheezing) • shock

Drug Facts (continued)

Also be warned: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take naproxen sodium or other pain relievers/fever reducers. Naproxen sodium may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer.

Ask a doctor before use if you have had serious side effects from any pain reliever.

Ask a doctor or pharmacist before use if you are: • taking any other product that contains naproxen sodium or any other pain reliever/fever reducer • taking other drugs on a regular basis • under a doctor's care for any continuing condition

Stop use and ask a doctor if: • an allergic reaction occurs. Seek medical help right away. • any new or unexpected symptoms occur • symptoms continue or worsen • you have difficulty swallowing or it feels like the pill is stuck in your throat • you develop hives • stomach pain occurs with use of this product or it feels like the pill is stuck in your throat • pain worsens or lasts for more than 10 days • painful areas are red or swollen

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use naproxen sodium during the last 3 months of pregnancy unless expressly directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions: • do not take more than directed • drink a full glass of water with each dose

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|----------------|--|
| over age 65 | 1 caplet every 12 hours |
| 12 to 65 years | Take 1 caplet every 8-12 hours. For the first dose you may take 2 caplets within the first hour. |
| under 12 years | Do not take more than 2 caplets in any 8 to 12 hours, or 3 caplets in 24 hour period. The smallest effective dose should be used. ask a doctor |

PS



**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