NDA 20-204/S-007

Bayer Consumer Care Division
Attention: Karen Mancuso
Assistant Director, Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

6 MAR 2001

Dear Ms. Mancuso:

Please refer to your supplemental new drug application dated June 3, 1998, received June 4, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve (naproxen sodium), 220mg.

We acknowledge receipt of your submission dated August 29, 2000.

This "Changes Being Effected" supplemental new drug application provides for product labeling for the sample and saleable pouch (1's) which incorporate the current "Allergy alert" and "Alcohol warning" statements.

We have completed the review of this supplemental new drug application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the labeling submitted on August 29, 2000. Accordingly, the supplemental new drug application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling dated August 29, 2000. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 10 of the copies on heavyweight paper or similar material. Alternatively, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-204/S-007." Approval of this submission by FDA is not required before the labeling is used.

We request that the following revisions in the labeling for this drug product be implemented within 180 days or at the next printing, whichever comes first:

1. Under the "Stop use and ask a doctor if:" statement, the first bulleted statement should be separated into two sentences to read "an allergic reaction occurs. Seek medical attention right away."

2. The statements “Store at room temperature: Avoid high humidity and excessive heat 104°F (40°C)” should be revised to read “Store at 20-25°C (68-77°F)” and “avoid high humidity and excessive heat 40°C (104°F)”.

Please revise the labeling for this drug product in accordance with the requirement of the March 17, 1999 FEDERAL REGISTER document “Over-the-Counter Human Drugs; Labeling Requirements; Final Rule (64 FR 13254) (OTC labeling final rule), which has been incorporated into the regulations at 21 CFR 201.66. We remind you that the labeling of your product must be revised to reflect the Drug Facts format within the timeframes specified in the OTC labeling final rule.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" 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

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 Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2247.

Sincerely,

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