DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-204/S-019

Bayer HealthCare LLC
Consumer Care Division
Attention: William R. Walsh
Associate Director, Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, New Jersey 07962-5000

Dear Mr. Walsh:

Please refer to your supplemental new drug application dated September 18, 2003, received September 22, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve (220 mg naproxen sodium) tablets.

This supplemental new drug application requests permission to discontinue the inclusion of package inserts throughout the product line.

We completed our review of this application. This application is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the last approved labeling (immediate container and carton labels), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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

If you have any questions, call Walter Ellenberg, Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Charles Ganley, M.D.
Director, Division of Over-the-Counter Drug Products
Center for Drug Evaluation and Research

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

/s/

Charles Ganley
3/22/04 10:29:16 AM