DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-204/S-031

Bayer HealthCare LLC
Consumer Care
Attention: Leonard Baum, R.Ph
Vice President, Head Global Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Dear Mr. Baum:

Please refer to your supplemental new drug application dated August 11, 2008, received August 12, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve (220 mg naproxen sodium) tablets.

We acknowledge receipt of your submissions dated August 28, and October 16, 2008.

This supplemental new drug application provides for a revised label configuration with a pull-out Drug Facts label for three non-child resistant (NCR) Aleve product count sizes to be used with redesigned bottles. The bottles were not submitted for approval as part of this supplement.

We have completed our review of this supplemental new drug application. This application is approved for the labels for the NCR Aleve 100-count caplet, 200-count tablet, and 40-count gelcaplet package sizes, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (100-count caplet, 200-count tablet, and 40-count gelcaplet bottle labels and 40-count carton label submitted October 16, 2008), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. 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. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 20-204/S-031**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that the new bottle shape is not being reviewed or approved under this supplement. Assuming that the change in bottle shape meets the criteria outlined in 21 CFR 314.70, you should report this change in your next annual report. Otherwise, you should submit an appropriate supplemental new drug application for this change.

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
Food and Drug Administration
Suite 12B05
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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Andrea Segal

11/24/2008 05:23:49 PM