DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-204/S-023

Bayer HealthCare LLC
Consumer Care Division
Attention: Leonard M. Baum, RPh
Vice President, 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 July 5, 2005, received July 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve (220 mg naproxen sodium) tablets and Midol Extended Relief (220 mg naproxen sodium) tablets.

We acknowledge receipt of your submissions dated, August 2 and 5, September 28, and October 11, 2005 and January 4 and 5, 2006.

This supplemental new drug application provides for revisions to the Principal Display Panel and Drug Facts label, and proposes the removal of dosing directions for adults over 65 years of age, for the Aleve 1-, 8-, and 100-count and Midol 24-count package sizes, in response to the June 14 and July 15, 2005 supplemental labeling request letters. According to your January 4, 2006 submission, the 100-count package size is representative of all package sizes employing the same labeling format under this NDA.

We have completed our review of this application, as amended. This application is approved for the Aleve 1-, 8-, and 100 count (which is representative for all package sizes employing the same format) and the Midol 24-count 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 draft labeling for Aleve (1-count pouch, 8-count blister card and immediate container label, and 100-count immediate container and carton labels submitted January 4, 2006) and Midol (24-count blister pack and carton label submitted January 5, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

In addition, increase the font size of the text and revise the Drug Facts labeling on the blister card used with the 8-count Aleve caplets in accordance to 21 CFR § 201.66(d)(1) – (d)(9) at the time of next printing.

Please submit an electronic version of the FPL for **all stock keeping units** 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-023**". Approval of this submission by FDA is not required before the labeling is used.

We remind you of your commitments, stated in your submission dated January 5, 2005, to make the following revisions to the Principal Display Panel (PDP):

1. For the Aleve product labels, while the combination of the box and text of the statement "See new warnings information" is one-third the size of the trade name, at the time of next printing or 180 days, whichever comes first, increase the text size of the "See new warning information" statement to one-third the size of the most prominent printed matter for all stock keeping units.

2. For the Midol product label, increase the text of the "See new warnings information" statement to be at least one-third the size of the most prominent printed matter at the time of initial printing.

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 Neel Patel, Regulatory Project Manager, at (301) 796-0970.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Acting Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription 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/

Andrea Segal

1/6/2006 02:42:35 PM