DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-204/S-032

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 October 16, 2008, received October 17, 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 February 13, March 20, and April 7, 2009.

We also refer to your email dated April 15, 2009 providing further explanation of the representative labeling.

This supplemental new drug application (NDA) provides for the revised cardiovascular warning statement "When using this product the risk of heart attack or stroke may increase if you use more than directed or for longer than directed" and the addition of the warning statement "Ask a doctor before use if you have asthma" to the Drug Facts label in response to the September 19, 2008 supplemental labeling request letters. This supplemental NDA also provides for revisions to the Midol Extended Relief product labeling to include all of the indications, warnings, and directions for approved OTC naproxen products.

We have completed our review of this supplemental new drug application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, for the Aleve 1-, 6-, 24- (representative of the 24-count caplet and tablet), and 50-count caplet (representative of the 50-, 100-, 150-, 200-, and 250-count caplet), and 8- and 50-count tablet (representative of the 50-, 100-, 150-, and 200-count tablet), and 40-count gelcap (representative of the 20-, 40- and 80-count gelcap), and the Midol Extended Relief 24-count caplet package sizes.

Submit final printed labeling for all represented stock keeping units, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labels (Aleve 1-count caplet front and back pouch labels, 6-count caplet carton label, 8-count tablet blister card, 24-count caplet (representative of 24-count caplet and tablet) carton label, 50-count caplet (representative of the 50-, 100-, 150-, 200-, and 250-count caplet) carton label, 50-count tablet (representative of the 50-, 100-, 150-, and 200-count tablet) carton label, and the 40-count gelcap

(representative of the 20-, 40- and 80-count gelcap) carton label submitted February 13, 2009, and the Aleve 150-, 200-, and 250-count caplet and 150-count tablet immediate container labels, 6-count caplet blister card, 8-count tablet vial label, and the Midol Extended Relief 24-count caplet carton label and blister card submitted April 7, 2009), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20-204/S-032**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and 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

4/15/2009 08:16:45 PM