DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020204/S-040

SUPPLEMENT APPROVAL

Bayer Healthcare LLC
Attention: Leonard M. Baum, R.Ph
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 (sNDA) dated September 21, 2011, received September 22, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® (naproxen sodium) tablets, 220 mg.

We acknowledge receipt of your amendment dated February 9, 2012

This "Prior Approval" supplemental new drug application proposes the following changes:

- Converting the Aleve 40-count gelatin coated capsule-shaped tablets (gelcaps) immediate container from a non-child resistant to a child resistant closure system
- Replacing the statement, "Easy Open Arthritis Cap" on the principle display panel (PDP) with "Soft Grip Arthritis Cap"
- Removal of the Arthritis Foundation's "Ease of Use Commendation" from the PDP
- Replacing the statement "This Package For Households Without Young Children" with "This Package is Child-Resistant" on the PDP
- Revision of the statement "12 Hours Strong" to "Strength to Last 12 Hours" and relocation of the statement on the PDP
- Removal of the "See new warnings information" flag from the PDP

Also, the proposed label reflects the changes submitted under Supplement 39 (shifted "strength to last 12 hours" banner, revised and shifted Bayer logo, added stylized arc).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

LABELING

Submit final printed labeling 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 enclosed labeling (Aleve® gelatin coated capsule-shaped tablets (gelcaps) 40-count carton and immediate container (bottle)

labels submitted on September 21, 2011), 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 (June 2008)." 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 020204/S-040**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

REPORTING REQUIREMENTS

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 LT James Lee, Regulatory Project Manager, at (301) 796-5283.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: Carton and Immediate Container Labeling

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

/s/

ANDREA LEONARD SEGAL
03/16/2012