



NDA 020204/S-039

**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 19, 2011, received September 20, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve<sup>®</sup> (naproxen sodium) tablet, 220 mg.

This "Prior Approval" supplemental new drug application provides for the following graphics changes on the principal display panel (PDP)

1. Extension of the banner containing the phrase "Strength to Last 12 Hours" along the entire bottom of PDP
2. Removal of the words "Bayer HealthCare" from the Bayer logo and a change in the location of the Bayer logo to above the banner
3. Addition of a stylized arc across the top of the PDP
4. Removal of the "See new warnings information" from the PDP

We have completed our review of this application. 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 the enclosed labeling submitted September 19, 2011, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Aleve<sup>®</sup> capsule-shaped tablets (caplets)

- 1-count immediate container (pouch) label
- 6-count immediate container (blister pack) and carton label
- 24-count immediate container (bottle) and carton label
- 50-count immediate container (bottle) and carton label
  - Representative of 100-, 150-, 200-, and 250-count immediate container (bottle) and carton labels

- 100-count non-child resistant immediate container (bottle) label
  - Representative of 200-count tab non-child resistant immediate container (bottle) label

Aleve<sup>®</sup> tablets

- 10-count immediate container (bottle) and carton (blister card) labels
- 24-count immediate container (bottle) and carton labels
- 50-count immediate container (bottle) and carton labels
  - Representative of 100-count immediate container (bottle) and carton labels

Aleve<sup>®</sup> gelatin-coated tablets (gelcaps)

- 20-count immediate container (bottle) and carton label
- 80- count immediate container (bottle) and carton labels
  - Representative of 40-count immediate container (bottle) and carton labels

FPL must be submitted for all representative count sizes. Representative labeling will not be acceptable in the FPL submission.

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-039.**” 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

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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ANDREA LEONARD SEGAL  
03/15/2012