



NDA 020204/S-037

SUPPLEMENT APPROVAL

Bayer Healthcare LLC
Attention: Kerri J. McMahon
Manager, Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962

Dear Ms. McMahon:

Please refer to your Supplemental New Drug Application (sNDA) dated October 8, 2010, received October 12, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve[®] (naproxen sodium) tablets, 220 mg.

This “Changes Being Effected” supplemental new drug application provides for the revised stomach bleeding warning as specified in the Organ-Specific Warnings final rule (21 CFR 201.326) and the removal of the scissors image and associated text from the Aleve[®] immediate container.

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 (5-count Midol[®] Extended Relief, and 6-count Aleve[®] capsule-shaped tablet (caplet) immediate container (blister pack) labels submitted on October 8, 2010) 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-037.**” Approval of this submission by FDA is not required before the labeling is used. Please note that representative labeling is not acceptable for Final Printed Labeling.

Even though no revisions were made to the 5-count Aleve[®] carton labels and 6-count Midol[®] carton labels, we request that you submit them as part of the FPL to this supplement in order to maintain a record of the complete labeling (all count sizes and packaging configurations) being approved as part of this supplement.

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.

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}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure: 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/

JOEL SCHIFFENBAUER
04/08/2011