



NDA 020204/S-035

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Leonard M. Baum
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 April 30, 2010, received May 3, 2010, 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 October 28, 2010

This “Changes Being Effected” supplemental new drug application provides for the addition of the organ-specific warnings specified in the Organ-Specific Warnings final rule (74 FR 19385) and the removal of the statement “do not take longer than 10 days, unless directed by a doctor (see new warnings)” per the FDA’s General Advice letter dated September 4, 2009.

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.

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 on April 30, 2010, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable:

Labeling Submitted April 30, 2010:

Aleve Capsule-Shaped Tablets (Caplets):

- 1-count immediate container (pouch) label
- 50-count - representative of the 24-, 100-, 150-, 200- and 250-count immediate container (bottle) labels
- 50-count - representative of the 24-, 100-, 150-, 200- and 250-count carton labels

Aleve Tablets:

- 10-count immediate container (vial)
- 50-count - representative of the 24-, 100-, 150-, and 200-count immediate container (bottle) labels

- 10-count carton label
- 50-count - representative of the 24-, 100-, 150-, and 200-count carton labels

Aleve Gelatin-Coated Capsule-Shaped Tablets (Gelcaps):

- 40-count - representative of the 20-, and 80-count immediate container (bottle) labels
- 40-count - representative for 20-, and 80-count) carton labels

Midol Capsule-Shaped Tablets (Caplets):

- 20-count carton label

Even though no revisions were made to the 20-count Midol Capsule-Shaped Tablets (Caplets) immediate container label, we request that you submit this immediate container label as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

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-035.**” Approval of this submission by FDA is not required before the labeling is used.

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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

Sincerely,

{See appended electronic signature page}

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

Enclosure: Carton and 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
11/03/2010