



NDA 020204/S-038

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Mary E. Williams
Senior Associate Director, Regulatory Affairs
36 Columbia Road
PO Box 1910
Morristown, NJ 07962-1910

Dear Ms. Williams:

Please refer to your Supplemental New Drug Application (sNDA) dated August 19, 2011, received August 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 amendments dated February 3, 2012, August 9, 2012, and January 24, 2013.

The August 9, 2012, submission constituted a complete response to our February 22, 2012, action letter.

This "Prior Approval" labeling supplemental new drug application proposes the following Changes for the SKUs specified in the Labeling Section of this letter:

1. The addition of peel-off Instant Redeemable Coupons (IRCs) to the carton labels and non-child resistant bottle labels.
2. A new packaging configuration that consists of two shrink wrapped cartons to be sold as one new stock keeping unit (SKU).
3. The addition of the statement "XX Free Caplets/Tablets" to the principal display panel (PDP) of the carton labels and non-child resistant bottle labels.

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 the following:

- 100 + 30-count capsule shaped tablet carton with bonus package flag submitted on August 9, 2012

- 50 + 15-count capsule shaped tablet carton with bonus package flag submitted on January 24, 2013
- 100 + 30-count tablet carton with bonus package flag submitted on August 9, 2012
- 100 + 30-count non-child resistant (non-CR) capsule shaped tablet immediate container (bottle) with bonus package flag submitted on August 9, 2012
- 150-count capsule shaped tablet carton shrink wrapped with 24-count capsule shaped tablet carton submitted on January 24, 2013
- 100-count tablet carton shrink wrapped with 24-count tablet carton submitted on January 24, 2013
- Instant Redeemable Coupon for the 200-count capsule shaped tablet carton submitted on August 9, 2012
- Instant Redeemable Coupon for the 200-count non-child resistant (non-CR) tablet immediate container (bottle) submitted on August 9, 2012

We also remind you of your commitment to ensure that all Drug Facts labeling is visible to the consumer for any shrink wrapped dual package configuration that you market.

Please submit 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-038**”. 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.

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 Celia Peacock, Regulatory Project Manager at (301) 796-4154.

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
02/07/2013