DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020204/S-042 **SUPPLEMENT APPROVAL**

Bayer HealthCare LLC
Attention: Scott Charvat
Manager, Global Technical Regulatory Affairs
36 Columbia Road
PO Box 1910
Morristown, NJ 07962-1910

Dear Mr. Charvat:

Please refer to your Supplemental New Drug Application (sNDA) dated July 2, 2012, received July 3, 2012, and 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 July 12, August 9, and December 18, 2012.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for the addition of a new packaging configuration (a 232.5 cc HDPE immediate container (bottle)), with a corresponding capsule-shaped tablet (caplet) count of 270, and associated labeling.

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 270-count carton and immediate container (bottle) labels submitted in the December 18, 2012 submission. Please note that the FPL should also reflect the location of the lot or control number on the immediate container (bottle) as provided in the August 9, 2012 submission. Please submit in the "Drug Facts" format (21 CFR 201.66), where applicable.

Please note that the "NEW Larger Size" flag should be removed from the principal display panel after 6 months of marketing.

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-042."** 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
01/03/2013