DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20204/S-053

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Amy Levitt
Senior Associate Director
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Levitt:

Please refer to your supplemental new drug application (sNDA) dated and received September 29, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® (naproxen sodium) tablet, 220 mg.

This "Prior Approval" supplemental new drug application provides for the addition of an instant rebate coupon (peel off) which can be redeemed at purchase of the product for the currently approved Aleve® products:

- 50-count outer carton container, tablet
- 50-count outer carton container, tablet (capsule-shaped tablet)
- 40-count outer carton container, tablet (gelatin-coated capsule-shaped tablet), SOFT GRIP™ Arthritis Cap

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 (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the following labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Date Submitted
Instant rebate coupon (peel off) on the principal display panel for 50-count tablet, 50-count tablet (capsule-shaped tablet) and 40-count tablet (gelatin-coated capsule-shaped tablet)	September 29, 2017
Tablet	
50-count immediate container, front and back	November 2, 2017
50-count outer carton container	November 2, 2017
Caplet (capsule-shaped tablet)	
50-count immediate container, front and back	November 2, 2017
50-count outer carton container	November 2, 2017
Gelcap (gelatin-coated capsule-shaped tablet)	
40-count immediate container, front and back, SOFT GRIP™ Arthritis Cap	November 2, 2017
40-count outer carton container, SOFT GRIP™ Arthritis Cap	November 2, 2017

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20204/S-053**." 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 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 Tinya Sensie, Regulatory Project Manager, at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
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/

KAREN M MAHONEY
03/27/2018