DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 020204/S-052

SUPPLEMENT APPROVAL

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

Dear Ms. Levitt:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 20, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® (naproxen sodium) tablets, 220 mg.

This "Prior Approval" supplemental new drug application provides for the addition of the cardiovascular risk warning in accordance with the Agency's CBE Request Letter dated August 18, 2016.

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 it is available, but no more than 30 days after it is printed. The FPL must be identical to the labeling listed below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	**Submission Date**
Tablet	
10-ct immediate container (vial) with backer card (front and back)	March 20, 2017
24-ct outer carton	March 20, 2017
24-ct immediate container	June 9, 2017
50-ct outer carton	March 20, 2017
50-ct immediate container	June 9, 2017
100-ct outer carton	March 20, 2017
100-ct immediate container	June 9, 2017

100+30-ct outer carton	March 20, 2017
100+30-ct immediate container	June 9, 2017
200-ct immediate container (stand-alone bottle)	June 9, 2017
200+50-ct immediate container (stand-alone bottle)	June 9, 2017
24+12-ct outer carton	March 20, 2017
24+12-ct immediate container	June 9, 2017
50+15-ct outer carton	March 20, 2017
50+15-ct immediate container	June 9, 2017
320-ct immediate container (stand-alone bottle)	June 9, 2017

Caplet (capsule-shaped tablet)	
1-ct immediate container (pouch)	March 20, 2017
1-ct immediate container (pouch) dispenser	March 20, 2017
6-ct outer carton	March 20, 2017
6-ct immediate container (blister card)	July 21, 2017
6-ct outer carton, Physician Sample, Manufacturer's Coupon, SAVE $2.00 On Any Aleve 20 ct or larger. Excludes Aleve PM and Aleve-D Cold Products (inside of outer carton container)	August 15, 2017
6-ct immediate container (bottle), Physician Sample	March 20, 2017
24-ct outer carton	March 20, 2017
24-ct immediate container	June 9, 2017
50-ct outer carton	March 20, 2017
50-ct immediate container	June 9, 2017
50+15-ct outer carton	March 20, 2017
50+15-ct immediate container	June 9, 2017
100-ct outer carton	March 20, 2017
100-ct immediate container	June 9, 2017
100-ct immediate container (stand-alone bottle), Easy Open Arthritis Cap	June 9, 2017
100+30-ct outer carton	March 20, 2017
100+30-ct immediate container	June 9, 2017
100+30-ct immediate container (stand-alone bottle), Easy Open Arthritis Cap	June 9, 2017
150-ct outer carton	March 20, 2017
150-ct immediate container	June 9, 2017
150-ct outer carton, SoftGrip Arthritis	March 20, 2017
150-ct immediate container, SoftGrip Arthritis	June 9, 2017
200-ct outer carton	March 20, 2017
200-ct immediate container	June 9, 2017
270-ct outer carton	March 20, 2017
270-ct immediate container	June 9, 2017
320-ct immediate container (stand-alone bottle)	March 20, 2017
24+12-ct outer carton	March 20, 2017
24+12-ct immediate container	June 9, 2017

50-ct outer carton, SoftGrip Arthritis	March 20, 2017
50-ct immediate container, SoftGrip Arthritis	June 9, 2017
270-ct outer carton, SoftGrip Arthritis	March 20, 2017
270-ct immediate container, SoftGrip Arthritis	June 9, 2017

Submitted Labeling	**Submission Date**
Gelcap (gelatin coated capsule-shaped tablet)	
40-ct outer carton, Soft Grip Arthritis	March 20, 2017
40-ct immediate container, Soft Grip Arthritis	June 9, 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 020204/S-052**." 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 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

ENCLOSURES:
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
09/14/2017