DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205352/S-009

SUPPLEMENT APPROVAL

Bayer Healthcare LLC Consumer Care
Attention: Dawn Jackman
Senior Associate Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, New Jersey 07981

Dear Ms. Jackman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received March 20, 2017, and your amendments, pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® PM (naproxen sodium, 220 mg and diphenhydramine HCl, 25 mg) tablets.

This "Changes Being Effected" sNDA provides for the addition of the heart attack and stroke warning to the Drug Facts labeling (DFL) in accordance with the "Changes Being Effected" (CBE-0) Request Letter from the Agency 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 as soon as they are available, but no more than 30 days after they are printed. The final printed labeling must be identical to the Aleve® PM (naproxen sodium, 220 mg and diphenhydramine HCl, 25 mg) submitted labeling, as identified in the table below; and, it must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission date
2-count immediate container (pouch)	March 20, 2017
72-count (36x2-count) pouch dispenser	March 20, 2017
20-count immediate container (bottle)	May 12, 2017
20-count carton	March 20, 2017
40-count immediate container (bottle)	May 12, 2017
40-count carton	March 20, 2017
40-count "Soft Grip Cap" (child resistant) immediate container (bottle)	May 12, 2017
40-count "Soft Grip Cap" carton	March 20, 2017
52-count (40+12) immediate container (bottle)	May 12, 2017
52-count (40+12) "12 Free Caplets" carton	March 20, 2017
80-count immediate container (bottle)	May 12, 2017
80-count carton	March 20, 2017
160-count carton (for use with two 80-count bottles)	March 20, 2017
96-count (80+16) immediate container (bottle)	May 12, 2017
96-count (80+16) "16 Free Caplets" carton	March 20, 2017
80-count "Easy Open Cap" (non-child resistant) immediate container (stand-alone bottle with no associated carton)	May 12, 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 205352/S-009**." 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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Immediate Container and Carton Labeling