DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 205352/S-011

SUPPLEMENT APPROVAL

Bayer Healthcare LLC
Attention: Dawn Jackman
Senior Associate Director, U.S. Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Jackman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received April 27, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® PM (naproxen sodium 220 mg and diphenhydramine hydrochloride 25 mg) tablet.

This "Prior Approval" supplemental new drug application proposes the following instantly redeemable coupons (IRCs):

- A $2 IRC placed on the 40-count carton
- A $2 IRC placed on the 40-count "Soft Grip Cap" carton
- A $3 IRC placed on the 80-count carton
- A $3 IRC placed on the 120-count "Soft Grip Cap" carton
- A $3 IRC hangtag placed on the 80-count stand-alone "Easy Open Cap" immediate container (bottle)
- A $3 IRC peel-off principal display panel (PDP) placed on the 80-count stand-alone "Easy Open Cap" immediate container (bottle)

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 labeling listed in the following table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission Date
$2.00 IRC, 40-ct or larger for 40-ct carton	June 13, 2018
$2.00 IRC, 40-ct or larger for 40-ct "Soft Grip Cap" carton	June 13, 2018
$3.00 IRC, 80-ct or larger for 80-ct carton	June 13, 2018
$3.00 IRC, 120-ct for 120-ct "Soft Grip Cap" carton	June 13, 2018
$3.00 IRC hangtag, 80-ct or larger for 80-ct "Easy Open Cap" immediate container	June 13, 2018
$3.00 IRC peel-off PDP, 80-ct or larger for 80-ct "Easy Open Cap" immediate container	June 13, 2018

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-011**." 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 Helen Lee, Regulatory Project Manager, at (301) 796-6848.

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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

KAREN M MAHONEY
08/28/2018