DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205352/S-004

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Consumer Care
Attention: Dawn Jackman
Associate Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Jackman:

Please refer to your Supplemental New Drug Application (sNDA) dated and received January 14, 2015, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve PM (naproxen sodium 220 mg and diphenhydramine hydrochloride 25 mg) tablets.

This sNDA provides for 24-, 25-, 26-, 48-, 50-, 52-, 96-, 100-, and 104-count package sizes and associated labeling offering free tablets to the consumer.

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. In all other aspects, the FPL must be identical to the carton and immediate container labeling submitted on June 16, 2015, and as listed in the following table, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Offer	Net Quantity
20 caplets with 4 free caplets	24-count
20 caplets with 5 free caplets	25-count
20 caplets with 6 free caplets	26-count
40 caplets with 8 free caplets	48-count
40 caplets with 10 free caplets	50-count
40 caplets with 12 free caplets	52-count
80 caplets with 16 free caplets	96-count
80 caplets with 20 free caplets	100-count
80 caplets with 24 free caplets	104-count

The FPL 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 205352/S-004**." 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 Jade Pham, Regulatory Project Manager at (301) 796-7031.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD
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
07/15/2015