DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205352/S-002

**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 May 23, 2014, received May 23, 2014, 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.

We acknowledge receipt of your amendment dated September 30, and October 16, 2014.

This supplemental application proposes labeling for two Aleve PM stock keeping units (SKUs):

1) Aleve PM with Soft Grip Cap (package is child-resistant), 40-count tablets
2) Aleve PM with Easy Open Cap (package not child-resistant), 80-count tablets

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 labels and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

- 40- and 80-count immediate container, back labels, submitted on May 23, 2014
- 40- and 80-count immediate container, front labels and 40-count outer carton label submitted on October 16, 2014

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-002**." Approval of this submission by FDA is not required before the labeling is used.

The banner with the term "NEW CAP" on the 40-count outer carton label and on the 80-count immediate bottle label may remain in place for six months of marketing and should be removed thereafter from the labeling.

## 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, M.D.
Deputy Director
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton and Container Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**

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/s/

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KAREN M MAHONEY
11/20/2014