DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 205352

NDA APPROVAL

Bayer HealthCare, LLC – Consumer Care
Attention: Leonard Baum,
Vice President, Regulatory Affairs – North America
36 Columbia Road, P.O. Box 1910
Morristown, NJ 07962

Dear Mr. Baum:

Please refer to your New Drug Application (NDA) dated March 20, 2013, received March 20, 2013 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 amendments dated March 28, April 18, May 15, July 3, 15, 17, August 7, September 30, November 8, 27, December 6, 2013 and January 9, 2014.

This NDA provides for the use of Aleve PM (naproxen sodium 220 mg and diphenhydramine hydrochloride 25 mg) tablets in adults and children 12 years and over for the following uses:

- for relief of occasional sleeplessness when associated with minor aches and pains
- helps you fall asleep and stay asleep.

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: 2-count pouch and the 20-, 40-, and 80- count immediate container (bottle, blister pack, lidding, etc.) and carton labels submitted on January 9, 2014 and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

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.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for age birth to less than 12 years because there is evidence suggesting that the drug product would be ineffective and unsafe in this population. This is because insomnia does not routinely occur in children except when it is associated with other disorders. A waiver is not required for adolescents aged 12 to 17 years because the product is labeled for use in this population.

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}

Theresa Michele, M.D.
Director
Division of Nonprescription Clinical Evaluation
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/

SHAW T CHEN
01/17/2014
on behalf of Terri Michele, Dir, DNCE