



NDA 205352/S-005

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 March 10, 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 two instant redeemable coupons (IRCs), each consisting of a factory applied peelable sticker and directions for placement. One IRC is affixed to the 20-count carton's principle display panel (PDP) and the other is affixed to the 40- and 80-count cartons' PDPs.

We have completed our review of this application. 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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and must be identical to the labeling submitted on March 10, 2015, listed as follows:

- 20-count carton IRC
- 20-count carton IRC placement instruction
- 40- and 80-count cartons IRC
- 40- and 80-count cartons IRC placement instruction

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-005.” 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):

20-count carton IRC labeling
20-count carton IRC placement instruction
40- and 80-count cartons IRC labeling
40- and 80-count cartons IRC placement instruction

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
08/14/2015