



NDA 205352/S-010

SUPPLEMENT APPROVAL

Bayer Healthcare LLC
Attention: Dawn Jackman
Senior Associate Director, U.S. Regulatory Affairs
100 Bayer Boulevard
Whippany, NJ 17981

Dear Ms. Jackman:

Please refer to your supplemental new drug application (sNDA) dated and received July 27, 2017, and your amendments, submitted pursuant to 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 “Changes Being Effected” sNDA proposes a new 120-count immediate container with Soft Grip® Cap and carton labeled with a child-resistant package statement.

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. We remind you to remove the “New Count Size” graphic from the carton label six months after marketing.

LABELING

Submit final printed labeling, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling 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
120-count Aleve® PM carton (bottle)	December 21, 2017
120-count Aleve® PM immediate container - Front (bottle)	July 27, 2017
120-count Aleve® PM immediate container – Back (bottle)	November 16, 2017

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-010.**” 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, 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 Laurie Buonaccorsi, Regulatory Project Manager, at (240) 402-6297.

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 and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
01/16/2018