



NDA 205352/S-015

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Danielle Larino
Associate Director, U.S. Regulatory Affairs
100 Bayer Boulevard, PO Box 915
Whippany, NJ 07981

Dear Ms. Larino:

Please refer to your supplemental new drug application (sNDA) dated and received May 5, 2020, and your amendment, 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 HCl 25 mg) tablet.

This Prior Approval supplemental new drug application provides for graphics changes for the currently approved 20-ct, 80-ct Easy Open Cap (no carton), and 120-ct with Soft Grip Cap principal display panel (PDP) and cartons (where applicable), change in orientation for the currently approved 20-ct carton, and addition of a new 50-ct stock keeping unit package size.

APPROVAL & LABELING

We have completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 enclosed labeling, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Submission Date
20-ct, immediate container, front and back labels	May 5, 2020
20-ct, outer carton	May 5, 2020
80-ct Easy Open Cap immediate container, front and back labels	May 5, 2020
120-ct Soft Grip Cap immediate container, front and back labels	May 5, 2020
120-ct Soft Grip Cap outer carton	May 5, 2020
50-ct immediate container, front and back labels	May 5, 2020
50-ct outer carton	May 5, 2020

The FPL should be submitted electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*.¹ For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 205352/S-015.**” 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 FDA.gov.² Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*. 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 LCDR Sally Doan, Regulatory Project Manager, at (301) 796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Deputy Director
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Carton and Container Labeling

¹ We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

² <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NUSHIN F TODD
10/30/2020 03:45:54 PM