



NDA 20204/S-057

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Amy Levitt
Sr. Associate Director
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Levitt:

Please refer to your supplemental new drug application (sNDA) dated and received January 26, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® (naproxen sodium) tablets/caplets/gelcaps, 220 mg.

This “Prior Approval” supplemental new drug application proposes an in-pack coupon for \$2.00 off the purchase of Aleve PM 20 count or larger, which will be placed in the cartons for the following Aleve products:

- Aleve 24 count tablets (approved September 14, 2017, S-052)
- Aleve 50 count tablets (approved September 14, 2017, S-052)
- Aleve 100 count tablets (approved September 14, 2017, S-052)
- Aleve 24 count caplets (approved September 14, 2017, S-052)
- Aleve 50 count caplets (approved September 14, 2017, S-052)
- Aleve 100 count caplets (approved September 14, 2017, S-052)
- Aleve 150 count caplets (approved September 14, 2017, S-052)
- Aleve 200 count caplets (approved September 14, 2017, S-052)
- Aleve 270 count caplets (approved September 14, 2017, S-052)

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 and with the following minor editorial revision:

The proposed statement used “660mg” as a dose limit, when it should read “660 mg” (i.e., a space is needed between 660 and mg). See the current and corrected statements below, the mistake is underlined.

Current:

Aleve PM contains an additional active ingredient not found in Aleve. Do not take Aleve and Aleve PM together or exceed 660mg of naproxen sodium in one day. Read the product labeling to determine if this product is appropriate for you to use.

Corrected:

Aleve PM contains an additional active ingredient not found in Aleve. Do not take Aleve and Aleve PM together or exceed 660 mg of naproxen sodium in one day. Read the product labeling to determine if this product is appropriate for you to use.

Please make this minor grammar correction to the coupon labeling submitted June 14, 2018 and submit the corrected label as final printed labeling (FPL).

LABELING

Submit final printed labeling (FPL), with the revision listed above, 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 identical to the following labeling:

Submitted Labeling	Date Submitted
In-pack \$2.00 off coupon for the purchase of Aleve PM	June 14, 2018

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 20204/S-057.**” 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 Tinya Sensie, Regulatory Project Manager, at (240) 402-4230.

Sincerely,

{See appended electronic signature page}

Theresa M. Michele, MD,
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. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

THERESA M MICHELE
07/25/2018