



NDA 20204/S-061

**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 August 2, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® Back and Muscle Pain (naproxen sodium) tablet, 220 mg.

This “Prior Approval” supplemental new drug application proposes labeling for new “bonus” presentations for Aleve Back and Muscle Pain (naproxen sodium) tablet, 220 mg.

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, 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 Aleve® Back and Muscle Pain (naproxen sodium) tablet, 220 mg labeling in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Labeling</b>	<b>Date Submitted</b>
36 (24+12) count outer carton	January 18, 2019
36 (24+12) count front immediate container (bottle) label	August 2, 2018
36 (24+12) count back immediate container (bottle) label	September 19, 2018
65 (50+15) count outer carton	January 18, 2019
65 (50+15) count front immediate container (bottle) label	August 2, 2018
65 (50+15) count back immediate container (bottle) label	September 19, 2018
130 (100+30) count outer carton	January 18, 2019
130 (100+30) count front and back immediate container (bottle) labels	August 2, 2018
150 (100+50) count outer carton	January 18, 2019
150 (100+50) count front and back immediate container (bottle) labels	August 2, 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 (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20204/S-061.**” 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}*

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

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**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.**  
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/s/  
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KAREN M MAHONEY  
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