

NDA 020204/S-067

**SUPPLEMENT APPROVAL**

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

Dear Ms. Levitt:

Please refer to your supplemental new drug application (sNDA) dated and received January 23, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve (naproxen sodium) tablets, 220 mg.

This Prior Approval sNDA provides for labeling for a new 225-ct (200+25-ct) bonus presentation for Aleve tablets in a stand-alone bottle with an Easy Open Arthritis Cap.

**APPROVAL & LABELING**

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 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 labels submitted on January 23, 2019 and April 15, 2019; and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Labeling</b>	<b>Date Submitted</b>
<ul style="list-style-type: none"> <li>225-ct (200+25-ct) Aleve tablets with Easy Open Arthritis Cap immediate container (stand-alone bottle) front label</li> </ul>	April 15, 2019
<ul style="list-style-type: none"> <li>225-ct (200+25-ct) Aleve tablets with Easy Open Arthritis Cap immediate container (stand-alone bottle) back label</li> </ul>	January 23, 2019
<ul style="list-style-type: none"> <li>In-pack \$1.00 off coupon toward the purchase of Aleve, Aleve Back &amp; Muscle Pain or Aleve Liquid Gels 80-ct</li> </ul>	January 23, 2019
<ul style="list-style-type: none"> <li>In-pack \$2.00 off coupon toward the purchase of Aleve, Aleve Back &amp; Muscle Pain or Aleve Liquid Gels 80-ct</li> </ul>	January 23, 2019

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*.<sup>1</sup> For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20204/S-067.**” 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.<sup>2</sup> 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).

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<sup>1</sup> 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>.

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

If you have any questions, call Sally Doan, Regulatory Project Manager, at 301-796-8025.

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

ENCLOSURES:

- 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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