

NDA 20204/S-081

**SUPPLEMENT APPROVAL**

Bayer HealthCare LLC  
Attention: Joanna Fleming  
Sr. Associate Director, Regulatory Affairs  
100 Bayer Boulevard  
Whippany, NJ 07981

Dear Ms. Fleming:

Please refer to your supplemental new drug application (sNDA) dated and received October 9, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve (naproxen sodium) tablet, 220 mg.

This Prior Approval sNDA provides for new packaging and labeling for 1-count pouches to be placed in a 48-count dispenser with graphic changes that align with approved labeling and new 1-count and 2-count sample pouches to be adhered to backer cards.

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

<b>Submitted Labeling</b>	<b>Date Submitted</b>
1-Count Aleve Caplets Pouch	October 09, 2020
48-Count Aleve Caplets Pouch Dispenser	March 09, 2021
1-Count Aleve Caplets Sample Pouch	October 09, 2020
Backer Card for 1-Count Aleve Caplets Sample Pouch	January 11, 2021
2-Count Aleve Caplets Sample Pouch	October 09, 2020
Backer Card for 2-Count Aleve Caplets Sample Pouch	January 11, 2021
1-Count Aleve Headache Pain Tablets Sample Pouch	October 09, 2020
Backer Card for 1-Count Aleve Headache Pain Tablets Sample Pouch	January 11, 2021

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-081.**” 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).

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  
Director (Acting)  
Division of Nonprescription Drugs I  
Office of Nonprescription Drugs  
Center for Drug Evaluation and Research

### ENCLOSURES:

- Carton and Container Labeling

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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>

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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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