



NDA 20204/S-088

**SUPPLEMENT APPROVAL**

Bayer HealthCare LLC  
Attention: Dr. Oliwier Nowak  
Senior Manager, Regulatory Affairs  
100 Bayer Boulevard, P.O. Box 915  
Whippany, NJ 07981-0915

Dear Dr. Nowak:

Please refer to your supplemental new drug application (sNDA) dated and received April 26, 2024, 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” supplemental new drug application provides for a line extension, specifically, addition of the proprietary name “Aleve Toothache Pain” and associated labeling for a 10-ct vial with backer card stock keeping unit.

**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 submitted on June 28, 2024, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

<b>Submitted Labeling</b>	<b>Date Submitted</b>
<b>Regular-shaped Tablets</b>	
Aleve Toothache Pain 10 Count Backer Card Label	April 26, 2024, amended June 28, 2024
Aleve Toothache Pain 10 Count Vial Label	April 26, 2024, amended June 28, 2024

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-088**”. 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, contact Myla Dellupac, RPh, Regulatory Project Manager, at (301) 837-7461 or myla.dellupac@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure:

Labeling (Backer Card and Immediate Container)

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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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