NDA 20204/S-084

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Madhuleena Bhadra
Manager, US Regulatory Affairs CMC
100 Bayer Boulevard, P.O. Box 915
Whippany, NJ 07981

Dear Ms. Bhadra:

Please refer to your supplemental new drug application (sNDA) dated and received May 6, 2022, 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 supplemental new drug application provides for a new formulation and manufacturing process.

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 described in the table below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
Regular-shaped Tablets	
10-count backer card (vial)	August 5, 2022
10-count vial label (stand-alone)	May 6, 2022
24-count carton	May 6, 2022
50-count carton	May 6, 2022
90-count carton	May 6, 2022
110-count (90 + 20 Free) carton	May 6, 2022
200-count easy open arthritis cap immediate container bottle label, *stand alone*	May 6, 2022
270-count carton	May 6, 2022
270-count immediate container bottle label	May 6, 2022
320-count soft grip arthritis cap immediate container bottle label, *stand alone*	May 6, 2022
Capsule-shaped Tablets	
6-count blister card carton	May 6, 2022
24-count carton	May 6, 2022
24-count soft grip arthritis cap immediate container bottle label, *stand-alone*	May 6, 2022
50-count carton	May 6, 2022
50-count soft grip arthritis cap carton	May 6, 2022
90-count carton	May 6, 2022
90-count easy open arthritis cap immediate container bottle label, *stand-alone*	May 6, 2022
110-count (90 + 20 Free) carton	May 6, 2022
110-count (90 + 20 Free) easy open arthritis cap immediate container bottle label	May 6, 2022
200-count carton	May 6, 2022
270-count immediate container bottle label, *stand alone*	May 6, 2022
270-count soft grip arthritis cap carton	May 6, 2022
270-count soft grip arthritis cap immediate container bottle label	May 6, 2022
320-count soft grip cap immediate container bottle label, *stand-alone*	May 6, 2022
1-count backer card – sample	August 5, 2022
1-count pouch – sample	May 6, 2022
2-count backer card – sample	August 5, 2022
2-count pouch - sample	May 6, 2022

1-count pouch	May 6, 2022
48-count pouch dispenser	May 6, 2022
60-count pouch dispenser	May 6, 2022
Aleve Back and Muscle Pain Tablets	
10-count vial label	May 6, 2022
24-count carton	May 6, 2022
50-count carton	May 6, 2022
90-count carton	May 6, 2022
110-count (90+20 Free) carton	May 6, 2022
200-count carton	May 6, 2022
200-count immediate container bottle label	May 6, 2022
250-count carton	May 6, 2022
250-count immediate container bottle label	May 6, 2022
Aleve Headache Pain Tablets	
1-count backer card - sample	August 5, 2022
1-count pouch - sample	May 6, 2022
24-count carton	May 6, 2022
50-count carton	May 6, 2022
90-count carton	May 6, 2022
175-count carton	May 6, 2022

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*.[1] For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 20204/S-084**." Approval of this submission by FDA is not required before the labeling is used.

[1] 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.

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.[2] 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
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton and Container Labeling

[2] 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.

/s/

NUSHIN F TODD
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