NDA 020204/S-089

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Oliwier Nowak, PharmD, MBA
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 November 8, 2024, 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 the addition of 24- and 50-count sizes under the approved proprietary name, "Aleve Toothache Pain".

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 in the "Drug Facts" format (21 CFR 201.66), where applicable and must be identical to the following labeling:

Submitted Labeling	**Date Submitted**
Aleve Toothache Pain	
Aleve Toothache Pain 24-count bottle immediate container label	January 16, 2025
Aleve Toothache Pain 24-count bottle carton	January 16, 2025
Aleve Toothache Pain 50-count bottle immediate container label	January 16, 2025
Aleve Toothache Pain 50-count bottle carton	February 11, 2025

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 020204/S-089**." 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.[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, contact Myla Dellupac, Regulatory Project Manager, at Myla.Dellupac@fda.hhs.gov or 301-837-7461.

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

[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.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

ENCLOSURE(S):

- Carton and Container Labeling

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

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
04/24/2025 02:29:41 PM