



NDA 20204/S-054

SUPPLEMENT APPROVAL

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

Dear Ms. Levitt:

Please refer to your supplemental new drug application (sNDA) dated and received October 12, 2017, 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 new stock keeping units (SKUs) and associated labeling:

- 100+50-count tablets
- 100+50-count capsule-shaped tablets (caplets)
- 100+50-count capsule-shaped tablets (caplets), Easy Open Arthritis Cap
- 100+100-count twin pack tablets (contains two previously approved outer cartons with immediate container [bottle] included in each outer carton)
- 100+100-count twin pack capsule-shaped tablets (caplets) (contains two previously approved outer cartons with immediate container [bottle] included in each outer carton)

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 agreed-upon labeling text.

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 following labeling, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable:

Submitted Labeling	Date Submitted
Tablet	
100+50-count immediate container (bottle), front and back	October 12, 2017
100+50-count outer carton container	October 12, 2017
100-count immediate container (bottle), front and back	October 12, 2017
100-count outer carton	October 12, 2017
100+100-count outer carton, twin pack	March 19, 2018
Caplet (capsule-shaped tablet)	
100+50-count immediate container(bottle), front and back	October 12, 2017
100+50-count outer carton container	October 12, 2017
100+50-count immediate container (stand-alone-bottle), capsule shaped tablet, Easy Open Arthritis Cap	October 12, 2017
100-count immediate container (bottle), front and back	October 12, 2017
100-count outer carton container	October 12, 2017
100+100-count outer carton container, twin pack	March 19, 2018

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 20204/S-054.**” 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 FPL, the content of labeling (Drug Facts) should be submitted in SPL format as described at

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

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. 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 Tinya Sensie, Regulatory Project Manager, at (240) 402-4230.

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

ENCLOSURE(S):

Carton and Container Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

KAREN M MAHONEY
03/29/2018