DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 20204/S-055

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 December 8, 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" sNDA provides for a 10-count tablet immediate container (vial) with peel-back Drug Facts Labeling (DFL) and outer container carton (tray display) 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 agreed-upon labeling text.

LABELING

Submit final printed labeling identical to the 10-count tablet immediate container vial label submitted on May 9, 2018, and the 100-count (10 x 10-count tablet) outer container (tray display) labeling for the 10-count immediate container (vial) submitted on May 29, 2018, as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the labels in the table below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable:

Submitted Labeling	Submission Dates
10-count immediate container (vial) with peel-back DFL	December 8, 2017 Revised: April 24, 2018 Revised: May 9, 2018
100-count (10 x 10-count) outer container (tray display labeling) for 10-count immediate container (vial) with peel-back DFL	May 29, 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-055**." Approval of this submission by FDA is not required before the labeling is used.

In the future, when submitting labeling for "loose" vials that are shipped to retailers and displayed in an outer container (e.g., tray display labeling), submit all of the proposed labeling in the sNDA.

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 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
06/08/2018