NDA 20204/S-066

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Verna Mecadon
Sr. Associate Director
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Mecadon:

Please refer to your supplemental new drug application (sNDA) dated and received January 8, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® Back & Muscle Pain (naproxen sodium, 220 mg) tablets.

This "Prior Approval" supplemental new drug application provides for two new Aleve® Back & Muscle Pain count sizes, and carton and container labeling, in 232.5 cc bottles with the 45 mm child-resistant cap.

- Aleve® Back & Muscle Pain 225 Count Tablets
- Aleve® Back & Muscle Pain 250 Count Tablets

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 labeling below, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
225-ct (200+25-ct) Aleve® Back & Muscle Pain tablets outer carton	April 3, 2019
225-ct (200+25-ct) Aleve® Back & Muscle Pain tablets front immediate container (bottle) label	January 8, 2019
250-ct Aleve® Back & Muscle Pain tablets outer carton	April 3, 2019
250-ct Aleve® Back & Muscle Pain tablets front immediate container (bottle) label	January 8, 2019
Rear peel-back label for both 225-ct (200+25-ct) and 250-ct Aleve® Back & Muscle Pain tablets immediate containers (bottles)	January 8, 2019

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-066**." 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).

[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

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

ENCLOSURES:

- Carton and Container Labeling

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/

KAREN M MAHONEY
07/02/2019 11:30:22 AM