NDA 020204/S-068

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Joanna Fleming
Associate Director
100 Bayer Boulevard
Whippany, NJ 07981

Dear Ms. Fleming:

Please refer to your supplemental new drug application (sNDA) dated and received February 22, 2019, 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 sNDA provides for labeling for a new 160-count size for Aleve gelatin-coated, capsule-shaped tablets (gelcaps) in a 118 cc stand-alone bottle with a non-child resistant cap ("Easy Open Arthritis Cap").

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.

We acknowledge your commitment to place the first commercial batch of the 160-ct presentation on long-term stability and to report the data in your annual report.

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 labels submitted on February 22, 2019; and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
160-count immediate container principal display panel (Aleve gelatin-coated, capsule-shaped tablets (gelcaps) stand-alone bottle with Easy Open cap)	February 22, 2019
160-count immediate container Drug Facts label (Aleve gelatin-coated, capsule-shaped tablets (gelcaps) stand-alone bottle with Easy Open cap)	February 22, 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-068**." Approval of this submission by FDA is not required before the labeling is used.

ADDITIONAL INFORMATION

Based on our review of your application, your drug product may have packaging that is subject to the requirements of the Poison Prevention Packaging Act (PPPA) (codified at 15 U.S.C. §§ 1471−1477), as well as its implementing regulations (Code of Federal Regulations, Title 16, Part 1700). Under section 502(p) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), a drug that has packaging or labeling that is in violation of a regulation issued pursuant to section 3 or 4 of the PPPA is deemed misbranded. We encourage you to consult the PPPA, as well its implementing regulations, in order to ensure the compliance of your drug product with respect to applicable special packaging (also known as child-resistant packaging) standards. If you have questions regarding compliance with the PPPA, please contact the U.S. Consumer Product Safety Commission (CPSC).

[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 LT Sally Doan, Regulatory Project Manager, at 301-796-8025.

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

[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/

KAREN M MAHONEY
08/07/2019 09:56:21 AM