NDA 205352/S-014

SUPPLEMENT APPROVAL

Bayer Healthcare LLC Consumer Care
Attention: Dawn Jackman
Senior Associate Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, New Jersey 07981

Dear Ms. Jackman:

Please refer to your supplemental new drug application (sNDA) dated and received November 7, 2019, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve® PM (naproxen sodium and diphenhydramine HCl) tablets.

This Changes Being Effected (CBE) supplemental new drug application provides for the addition of "[bullet] taking aspirin for heart attack or stroke, because naproxen may decrease this benefit of aspirin" under the ***Warnings*** subheading, "**Ask a doctor or pharmacist before use if you are**", in accordance with the Agency's May 9, 2019, CBE Supplement Request Letter.

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

Submitted Labeling	Dates Submitted
20 Count Carton	November 7, 2019
40 Count Carton	November 7, 2019
40 Count Soft Grip Cap Carton	November 7, 2019
40 + 12 Count Carton	November 7, 2019
80 Count Carton	November 7, 2019

Back Bottle Label for 80 Count Easy Open Cap (Stand-alone bottle)	November 7, 2019
Front Bottle Label for 80 Count with Easy Open Cap (Stand-alone bottle)	November 7, 2019
80 + 16 Count Carton	November 7, 2019
120 count Soft Grip Cap Carton	November 7, 2019
160 Count Carton	November 7, 2019
20 Count Front and Back Panel Bottle Label	November 7, 2019
40 Count Front and Back Panel Bottle Label	November 7, 2019
40 Count Soft Grip Cap Front and Back Panel Bottle Label	November 7, 2019
40+12 Count Front and Back Panel Bottle Label	November 7, 2019
80 Count Front and Back Panel Bottle Label	November 7, 2019
80 + 16 Count Front and Back Panel Bottle Label	November 7, 2019
120 Count Soft Grip Cap Front and Back Panel Bottle Label	November 7, 2019
160 Count Front and Back Panel Bottle Label (2x80 count Bottles)	November 7, 2019
Inner Bottle Foil Seal	January 17, 2020

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 205352/S-014.**" Approval of this submission by FDA is not required before the labeling is used.

[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 Dr. Helen Lee, Acting Safety Regulatory Project Manager, at 301-796-6848

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
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/

VALERIE S PRATT
04/06/2020 12:29:06 PM