NDA 20204/S-083

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Oliwier Nowak, PharmD, RAC
Manager, Regulatory Affairs
PO Box 915
100 Bayer Boulevard
Whippany, NJ 07981

Dear Dr. Nowak:

Please refer to your supplemental new drug application (sNDA) dated and received October 21, 2021, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve (naproxen sodium) tablets, 220 mg.

This "Changes Being Effected" supplemental new drug application provides for an update under the "If pregnant or breast-feeding" warning in the Drug Facts labeling in response to the Agency's CBE Supplement Request letter dated April 28, 2021.

APPROVAL & LABELING

We have completed our review of this application. 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 in the "Drug Facts" format (21 CFR 201.66), where applicable, and identical to the labeling listed in the table below:

Submitted Labeling	**Date Submitted**
Regular-shaped Tablets	
10 count vial label	October 21, 2021
10 count vial with backer card	October 21, 2021
24 count carton	October 21, 2021
50 count carton	October 21, 2021
110 count (90+20 Bonus) carton	October 21, 2021
90 count carton	October 21, 2021
200 count easy open arthritis cap bottle	October 21, 2021
270 count bottle label	October 21, 2021
270 count carton	October 21, 2021
320 count soft grip arthritis cap bottle	October 21, 2021

Capsule-shaped Tablets	
6 count blister card carton	October 21, 2021
24 count carton	October 21, 2021
50 count carton	October 21, 2021
90 count carton	October 21, 2021
200 count carton	October 21, 2021
200 count bottle label	October 21, 2021
110 count (90+20 Bonus) carton	October 21, 2021
270 count bottle label	October 21, 2021
24 count soft grip arthritis bottle	October 21, 2021
50 count soft grip arthritis carton	October 21, 2021
270 count soft grip arthritis bottle carton	October 21, 2021
270 count soft grip arthritis bottle label	October 21, 2021
90 count easy open arthritis cap bottle	October 21, 2021
110 count (90+20 Bonus) easy open arthritis cap	October 21, 2021
320 count with yellow (“soft grip”) cap	October 21, 2021
Backer card for 1 count sample	October 21, 2021
1 count sample pouch	October 21, 2021
Backer card for 2 count sample	October 21, 2021
2 count sample pouch	October 21, 2021
48 count pouch dispenser	October 21, 2021
1 count pouch	October 21, 2021
60 count pouch dispenser	October 21, 2021
Back and Muscle Pain Tablets	
10 count vial	October 21, 2021
24 count carton	October 21, 2021
50 count carton	October 21, 2021
90 count carton	October 21, 2021
200 count bottle label	October 21, 2021
200 count carton	October 21, 2021
250 count carton	October 21, 2021
250 count bottle label	October 21, 2021
110 count (90+20 Bonus) carton	October 21, 2021
Headache Pain Tablets	
24 count carton	October 21, 2021
50 count carton	October 21, 2021
90 count carton	October 21, 2021
175 count carton	October 21, 2021
175 count bottle label	October 21, 2021
Backer card for 1 count sample	October 21, 2021
1 count sample pouch	October 21, 2021
Gelatin Coated Capsule Shaped Tablets	
40 count easy open arthritis cap carton	October 21, 2021
90 count carton	October 21, 2021

160 count easy open arthritis cap bottle label	October 21, 2021
Menstridol	
20 count carton	October 21, 2021

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-083**." 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 are 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 Helen Lee, Safety Regulatory Project Manager, at 301-796-6848.

[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

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

ENCLOSURE(S):

- 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/

VALERIE S PRATT
03/10/2022 11:53:09 AM