



NDA 20204/S-071

SUPPLEMENT APPROVAL

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

Dear Ms. Fleming:

Please refer to your supplemental new drug application (sNDA) dated and received November 6, 2019, and your amendment, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve (naproxen sodium) tablet, 220 mg.

This Prior Approval supplemental new drug application provides for updated labeling, in response to a Changes Being Effected supplement request letter to update nonprescription naproxen labeling to inform consumers of the risks of thromboxane inhibition during concurrent therapy with low-dose aspirin and naproxen sodium, and for additional labeling changes related to product promotion.

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, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Submitted Labeling	Date Submitted
Regular-shaped tablets	
10-ct vial with backer card (outer container)- Aleve regular-shaped tablets	November 6, 2019
10-ct vial (immediate container)- Aleve regular-shaped tablets	November 6, 2019
24-ct carton (outer container)- Aleve regular-shaped tablets	November 6, 2019
24-ct bottle (immediate container)- Aleve regular-shaped tablets	November 6, 2019
50-ct carton (outer container)- Aleve regular-shaped tablets	November 6, 2019

50-ct bottle (immediate container)- Aleve regular-shaped tablets	November 6, 2019
100-ct carton (outer container)- Aleve regular-shaped tablets	November 6, 2019
100-ct bottle (immediate container)- Aleve regular-shaped tablets	November 6, 2019
24+12 count carton (outer container)- Aleve regular-shaped tablets	November 6, 2019
24+12 count bottle (immediate container)- Aleve regular-shaped tablets	November 6, 2019
50+15 count carton (outer container)- Aleve regular-shaped tablets	November 6, 2019
50+15 count bottle (immediate container)- Aleve regular-shaped tablets	November 6, 2019
100+30 count carton (outer container)- Aleve regular-shaped tablets	November 6, 2019
100+30 count bottle (immediate container)- Aleve regular-shaped tablets	November 6, 2019
100+50 count carton (outer container)- Aleve tablets	February 6, 2020
100+50 count bottle (immediate container)- Aleve tablets	February 6, 2020
200-ct <i>Easy Open Arthritis cap</i> (stand-alone bottle)- Aleve regular-shaped tablets	November 6, 2019
200+25 count <i>Easy Open Arthritis cap</i> (stand-alone bottle)- Aleve regular shaped tablets	November 6, 2019
200+50 count <i>Easy Open Arthritis cap</i> (stand-alone bottle)- Aleve regular shaped tablets	November 6, 2019
320-ct <i>Soft Grip Arthritis cap</i> (stand-alone bottle)- Aleve regular shaped tablets	November 6, 2019
Capsule-shaped tablets	
48-ct pouch dispenser carton (outer container)- Aleve capsule-shaped tablets	November 6, 2019
1-ct pouch (immediate container)- Aleve capsule-shaped tablets	November 6, 2019
6-ct blister card carton (outer container)- Aleve capsule-shaped tablets	November 6, 2019
6-ct blister (immediate container) - Aleve capsule capsule-shaped tablets	November 6, 2019
6-ct <i>physician sample</i> carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
6-ct <i>physician sample</i> bottle (immediate container)-Aleve capsule-shaped tablets	November 6, 2019
24-ct carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
24-ct bottle (immediate container)- Aleve capsule-shaped tablets	November 6, 2019
50-ct carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019

50-ct bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
100-ct carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
100-ct bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
200-ct carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
200-ct bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
270-ct carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
270-ct bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
24+12 count carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
24+12 count bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
50+15 count carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
50+15 count bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
100+30 count carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
100+30 count bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
100+50 count carton (outer container)- Aleve capsule-shaped tablets	February 6, 2020
100+50 count bottle (immediate container)- Aleve capsule-shaped tablets	February 6, 2020
200+25 count carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
200+25 count bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
50-ct <i>Soft Grip Arthritis cap</i> carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
50-ct <i>Soft Grip Arthritis cap</i> bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
150-ct <i>Soft Grip Arthritis cap</i> carton (outer container) - Aleve capsule-shaped tablets	November 6, 2019
150-ct <i>Soft Grip Arthritis cap</i> bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019
270-ct <i>Soft Grip Arthritis cap</i> carton (outer container) Aleve capsule-shaped tablets	November 6, 2019
270-ct <i>Soft Grip Arthritis cap</i> bottle (immediate container) - Aleve capsule-shaped tablets	November 6, 2019

100-ct <i>Easy Open Arthritis cap</i> (stand-alone bottle) - Aleve capsule-shaped tablets	November 6, 2019
100+30 count <i>Easy Open Arthritis cap</i> (stand-alone bottle) - Aleve capsule-shaped tablets	November 6, 2019
320-ct (stand-alone bottle) - Aleve capsule-shaped tablets	November 6, 2019
Back & Muscle Pain regular-shaped tablets	
10-ct vial (immediate container)-Aleve Back and Muscle Pain regular-shaped tablets	November 6, 2019
24-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
24-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
50-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
50-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
100-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
100-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
24+12 count carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
24+12 count bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
50+15-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
50+15-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
100+30-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
100+30 count bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
100+50 count carton (outer container)- Aleve Back and Muscle Pain tablets	February 6, 2020
100+50 count bottle (immediate container)- Aleve Back and Muscle Pain tablets	February 6, 2020
200-ct carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
200-ct bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
200+25 count carton (outer container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019
200+25-count bottle (immediate container)-Aleve Back and Muscle Pain regular shaped tablets	November 6, 2019

250 count carton (outer container)- Aleve Back and Muscle Pain tablets	February 6, 2020
250 count bottle (immediate container)- Aleve Back and Muscle Pain tablets	February 6, 2020
Aleve gelatin coated capsule-shaped tablets	
40-ct <i>Soft Grip Arthritis cap</i> carton (outer container)-Aleve gelatin coated capsule-shaped tablets	November 6, 2019
40-ct <i>Soft Grip Arthritis cap</i> bottle (immediate container)-Aleve gelatin coated capsule-shaped tablets	November 6, 2019
160-ct <i>Easy Open Arthritis cap</i> (stand-alone bottle)-Aleve gelatin coated capsule-shaped tablets	November 6, 2019
Menstridol	
20-ct carton (outer container)-Menstridol capsule-shaped tablets	November 6, 2019
Inner bottle foil seal	
Inner bottle foil seal	February 6, 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 20204/S-071.**” 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 LT Sally Doan, Regulatory Project Manager, at 301-796-8025.

Sincerely,

{See appended electronic signature page}

Nushin Todd, MD, PhD
Acting Deputy Director, Division of Nonprescription Drugs I
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/

NUSHIN F TODD
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