



NDA 21076/S-017

SUPPLEMENT APPROVAL

Bayer HealthCare LLC
Attention: Dawn Jackman
Senior Associate Director, Regulatory Affairs
100 Bayer Blvd
Whippany NJ, 07981

Dear Ms. Jackman:

Please refer to your supplemental new drug application (sNDA) dated and received October 21, 2021, and your amendment, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Aleve-D Sinus & Cold and Aleve-D Sinus & Headache (naproxen sodium 220 mg and pseudoephedrine HCl 120 mg), extended release tablets.

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, 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 in the “Drug Facts” format (21 CFR 201.66), where applicable, and identical to the 10-count Aleve-D Sinus & Cold and 10-count Aleve-D Sinus & Headache carton labels submitted on October 21, 2021.

In addition, submit the immediate container (blister pack) labels for the 10-count Aleve-D Sinus & Cold and 10-count Aleve-D Sinus & Headache stock keeping units as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

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 21076/S-017.**” 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.

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 Labeling

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>

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
03/02/2022 02:17:30 PM