NDA 21076/S-019

**SUPPLEMENT APPROVAL**

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

Dear Ms. Jackman:

Please refer to your supplemental new drug application (sNDA) dated and received January 20, 2023, submitted under section 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 tablet.

This "Changes Being Effected" supplemental new drug application provides an update under the "If pregnant or breast-feeding" warning in the Drug Facts labeling for the 20-count Aleve-D Sinus & Cold carton. The change in labeling was 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 following:

| Submitted Labeling | Date Submitted |
|---|---|
| 20-count carton (outer container) | January 20, 2023 |

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-019**." 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 Helen Lee, PharmD, Regulatory Project Manager, at 301-796-6848.

Sincerely,

*{See appended electronic signature page}*

Jody Green, MD
Deputy Director for Safety
Division of Nonprescription Drugs I
Office of Nonprescription Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton Labeling

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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.**

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/s/

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