NDA 021076/S-016

SUPPLEMENT APPROVAL

Bayer HealthCare, LLC
Attention: Joanna Fleming
Sr. Associate Director, Regulatory Affairs
100 Bayer Boulevard
Whippany, New Jersey 07981

Dear Ms. Fleming:

Please refer to your supplemental new drug application (sNDA) dated and received October 18, 2019, 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 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. 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 10-count Aleve-D® Sinus and Cold and 10-count Aleve-D® Sinus and Headache carton labels submitted on October 18, 2019. In order to maintain a record of the complete labeling (count sizes and packaging configurations) approved as part of this supplement submit: the 20-count Aleve-D® Sinus and Cold carton and immediate container label, the immediate container (blister pack) labels for the 10-count Aleve-D Sinus and Cold and the 10-count Aleve-D® Sinus and Headache SKUs. The FPL must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

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-016.**" 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

U.S. Food and Drug Administration
Silver Spring, MD 20993
www.fda.gov

If you have any questions, call Dr. Helen Lee, Acting Safety Regulatory Project Manager, at 301-796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products I
Office of Nonprescription Drug Products
Center for Drug Evaluation and Research

ENCLOSURES:

- 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
04/06/2020 12:24:47 PM