DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-076/S-013

Bayer Healthcare LLC
Attention: Laura M. Yelvigi, Pharm.D.
Associate, Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Dear Ms. Yelvigi:

Please refer to your supplemental new drug application dated February 1, 2008, received February 4, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve Cold & Sinus (naproxen sodium 220 mg, pseudoephedrine HCl 120 mg) extended-release tablets.

We acknowledge receipt of your submissions dated July 3 and 30, 2008.

This supplemental application provides for a new trade name, Aleve-D Sinus & Cold, to replace the current trade name, Aleve Cold & Sinus. In your submission of July 3, 2008, you included labeling for the trade name, Aleve-D Sinus & Headache, to replace the additional current trade name for the product, Aleve Sinus & Headache.

We have completed our review of this application, as amended. This supplement is approved effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the revision listed below.

> Revise the blister pack label for Aleve-D Sinus & Headache from "Aleve-D" to "Aleve-D Sinus & Headache".

In your letter of July 30, 2008, you committed to making the above change. You should revise the blister pack label with the above requested revision at the time of next printing, or within 180 days, whichever come first. The revised label can be submitted in the next annual report.

The final printed labeling (FPL) must be identical to, and include the revisions listed, the submitted labeling (10- and 20-count carton and blister pack label for Aleve-D Sinus & Cold and 10-count carton and blister pack label for Aleve-D Sinus & Headache submitted July 30, 2008), and must be formatted in accordance with the applicable requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-076/S-013**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
WO22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

We remind you that you must comply with the requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Joel Schiffenbauer

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