DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-076/S-014

Bayer HealthCare Consumer Care
Attention: Leonard M. Baum, R.Ph.
Vice President, Head-Global Regulatory Affairs
36 Columbia Road
P.O. Box 1910
Morristown, NJ 07962-1910

Dear Mr. Baum:

Please refer to your supplemental new drug application dated October 16, 2008, received October 17, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve-D Sinus & Cold and Aleve-D Sinus & Headache (naproxen sodium, 220 mg and pseudoephedrine HCl, 120 mg) extended-release tablets.

This supplemental new drug application provides for the following changes to the drugs facts label:

1. under the ***Warnings*** section, addition of the statement "Ask a doctor before use if you have [bullet] asthma"
2. under the ***Warnings*** section, revision of the statement "When using this product [bullet] long term continuous use may increase the risk of heart attack or stroke" to "When using this product [bullet] the risk of heart attack or stroke may increase if you use more than directed or for longer than directed"
3. under the ***Warnings*** section, addition of the statement "Do not use [bullet] in children under 12 years of age"; and
4. under the ***Directions*** section, revision of the statement "[bullet] children under 12 years: ask a doctor" to "[bullet] children under 12 years: do not use"

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (Aleve-D Sinus & Cold (10- and 20-count cartons) and Aleve-D Sinus and Headache (10-count carton), submitted on October 15, 2009), and must be formatted in accordance with the requirements of 21 CFR 201.66 where applicable.

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-014**." 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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Janice Adams-King, Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, M.D.
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Andrea Segal

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