



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-076/S-011

Bayer HealthCare LLC
Consumer Care Division
Attention: Leonard M. Baum, RPh
Vice President, 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 July 5, 2005, received July 6, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve Cold & Sinus (220 mg naproxen sodium and 120 mg pseudoephedrine HCl) extended release tablets and Aleve Sinus & Headache (220 mg naproxen sodium and 120 mg pseudoephedrine HCl) extended release tablets.

We acknowledge receipt of your submissions dated, August 2, 5, and 11, September 28 and 29, 2005 and January 4 and 5, 2006.

This supplemental new drug application provides for revisions to the Principal Display Panel and Drug Facts label for the Aleve Cold and Sinus and Aleve Sinus & Headache 20-count package size in response to the June 14 and July 15, 2005 supplemental labeling request letters. According to your January 4, 2006 submission, this labeling is also representative of the 10-count package size.

We have completed our review of this application, as amended. This application is approved for the 20-count package size, which is representative of the 10-count package size, 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 draft labeling (20-count carton labels, blister packs, and package inserts submitted January 4, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL for **all stock keeping units** 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-011**". Approval of this submission by FDA is not required before the labeling is used.

We remind you of your commitment, stated in your submission dated January 5, 2005, to make the following revision to the Principal Display Panel:

While the combination of the box and text of the statement “See new warnings information” is one-third the size of the trade name, at the time of next printing or 180 days, whichever comes first, increase the text size of the “See new warning information” statement to one-third the size of the most prominent printed matter for all stock keeping units.

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, HFD-410
FDA
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 Elaine Abraham, Regulatory Project Manager, at (301) 796-0843.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Acting 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/

Andrea Segal

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