DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-076/S-007

Bayer Corporation
Consumer Care Division
36 Columbia Road
Morristown, New Jersey 07962-1910

Attention: Joanne Robinett
Director, Regulatory Affairs

Dear Ms. Robinett:

Please refer to your supplemental new drug application dated February 20, 2002, received February 21, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve Cold & Sinus (naproxen sodium /pseudoephedrine HCl) Extended-Release Tablet.

This supplemental new drug application provides for a new sub-brand name "Aleve Sinus & Headache."

We completed our review of this supplemental new drug application, and it is approved effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 20, 2002.

We request that you submit one copy of the introductory promotional materials you propose to use for this product to the Division of Over-the-Counter Drug Products. Submit all proposed materials in draft or mock-up form, not final print.

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Elaine Abraham, Regulatory Project Manager, at (301) 827-2301.

Sincerely,
{See appended electronic signature page}

Linda M. Katz, M.D., M.P.H.
Deputy Director
Division of Over the Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research
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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Linda Katz

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