DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-204/S-016

Bayer Corporation Consumer Care Division
Attention: William R. Walsh
Manager, Regulatory Affairs
36 Columbia Road
Morristown, New Jersey 07962

Dear Mr. Walsh:

Please refer to your supplemental new drug application dated February 28, 2002, and received March 1, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aleve Tablets/Capsuls/Gelcaps (naproxen sodium 220mg).

This "Changes Being Effected in 30 days" supplemental new drug application proposes a new vial for the 8- and 12-count package sizes to be packaged by a new facility. This application also provides revised labeling for the 8-count package size.

We have completed the review of this supplemental application, and it is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (immediate container and carton labels for the 8-count package submitted February 28, 2002), and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-204/S-016." Approval of this submission by FDA is not required before the labeling is used.

Draft labeling for your other package sizes has not been submitted. If you wish to market other package sizes with revised labeling as proposed in this application for the 8-count package, you must submit a supplemental application to provide revised labeling for the other package sizes.

We recommend the following labeling revisions to the approved draft labeling to be incorporated at the time of the next printing or in the final printed labeling.

1. The font size of the established name of the drug (naproxen sodium), the potency (220 mg), and the pharmacological categories (Pain reliever/fever reducer) should be increased to a size more reasonably related to the trade name to meet the requirements in 21 CFR 201.61.

2. The pregnancy warning on the card should be revised so that only the first four words of the warning are in boldface type.

3. For the allergy alert statement on the vial label, the "A" in "Alert" should be lower case, as in the blister card labeling.

4. Under ***Warnings***, there are several minor differences between the labeling in this submission and the prototype label for naproxen sodium provided on March 26, 2001, as an example for the February 21, 2001, draft Guidance to Industry entitled "Labeling OTC Human Drug Products – Updated Labeling in ANDAs." A period should not appear at the end of the ***Warnings*** subsections **Do not use** and **Ask a doctor before use.** Under ***Warnings***, **Stop use and ask a doctor if**, the word "for" should be removed from the phrase "or lasts *for* more than 10 days."

5. The storage statement has been revised from:

   "Store at room temperature: avoid high humidity and excessive heat 104ºF(40ºC)."

   to

   "store at 20-25ºC (68-77ºF). Avoid high humidity and excessive heat 40ºC (104ºF)"

   and it now appears under ***Other information***. The word "above" should be inserted after the word "heat."

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Walter Ellenberg, Ph.D., Regulatory Health Project Manager, at 301-827-2279.

Sincerely yours,

{See appended electronic signature page}

Charles Ganley, M.D.
Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Charles Ganley
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