DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-802

Bristol-Meyers Squibb
Worldwide Consumer Medicines
Attention: Donna Coughlin
Associate Director, Regulatory Affairs
1350 Liberty Avenue
Hillside, New Jersey 07205

Dear Ms. Coughlin:

Please refer to your supplemental new drug application dated December 13, 2002, received December 16, 2002, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Excedrine Migraine, (acetaminophen 250 mg, aspirin 250 mg, and caffeine 65 mg) tablets.

We acknowledge receipt of your submission dated December 16, 2002.

This "Changes Being Effected" supplemental new drug application amends the labeling for Excedrine Migraine to increase the safe use of the product as follows:

- Increase the point size of the established name of the drug on the PDP.
- Emphasize the active ingredients in the Drug Facts portion of the labeling through the use of shading.
- Add several warning statements regarding concomitant use of the product with other products containing acetaminophen.
- Amend the directions to add a statement instructing consumers to avoid taking more than the directed and to read the overdose statement.

The sponsor also revised the inactive ingredient disclosure to comply with a USP nomenclature change and reformatted the disclosure using asterisks to identify those ingredients that may be contained in the product.

We completed our review of this application, as amended. 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 (container and carton labels submitted December 16, 2002,) and must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit the FPL electronically 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, in no case 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 20-802/S-009." Approval of this submission by FDA is not required before the labeling is used.

The Agency is concerned about the need for organ-specific warnings for OTC drug products containing analgesic/antipyretic active ingredients. The Agency will provide guidance on wording and placement of organ-specific warnings in the labeling of drug products containing acetaminophen and/or NSAID's in the future.

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, 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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Walter Ellenberg, M.S., Ph.D., Regulatory Project Manager, at (301) 827-2241.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D.
Deputy 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/

Curtis Rosebraugh
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