HFD-310 REG-74

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

WARNING LETTER

MAY 8 1998

Bristol-Meyers Squibb Co.
345 Park Avenue
New York, New York 10154

Ref: 98-HFD-312-03

Dear Mr.

This is in reference to **"Excedrin EXTRA STRENGTH"** marketed by your firm for over-the-counter (OTC) drug use in the temporary relief of minor pain and to **"Excedrin MIGRAINE,"** which is the subject of a new drug application (NDA No. 20-802) recently approved by the Food and Drug Administration (FDA) for temporary relief of mild to moderate pain associated with migraine headache.

"Excedrin EXTRA STRENGTH" is currently featured in advertising for **"Excedrin MIGRAINE."** The advertising describes these two products as having the same formula, and that it is effective in relieving migraine headache pain. The identical nature of the formulations is emphasized, for example, through side-by-side depictions of their cartons and in describing these products as differing only in packaging and product use information.

It would be reasonable to assume that at least some consumers would conclude from this advertising that **"Excedrin EXTRA STRENGTH,"** like **"Excedrin MIGRAINE,"** is useful for temporary relief of mild to moderate pain associated with migraine headache, leading to its use for these indications. However, only the labeling for **"Excedrin MIGRAINE"** bears the necessary indications, directions, and warnings for the safe use of this product by the general public. In this regard, we are concerned that, in the absence of appropriate labeling, these consumers may be at increased risk of an adverse outcome.

Since **"Excedrin EXTRA STRENGTH"** is represented and suggested for temporary relief of mild to moderate pain associated with migraine headache, but does not bear adequate directions and warnings on its labeling, as described above, it is misbranded under sections 502(f)(1) and 502(f)(2) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above described violations of the Act are not meant to be an all-inclusive list of deficiencies by your firm. It is your responsibility to ensure that all drug products manufactured and distributed by your firm are in compliance with the Act. Federal agencies are advised of the issuance of all warning letters about drugs and devices so that they may take this information into account when considering the award of contracts.

We request that you take action immediately to correct these violations. Failure to do so may result in regulatory action without further notice. This action may include seizure and/or injunction.

Please respond to this office in writing within fifteen (15) working days of receipt of this letter. Your response should describe the specific actions you will take, or have taken, to correct the violations. Your response should also include an explanation of each step being taken to prevent recurrence of similar violations. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed. Your reply should be addressed to the Food and Drug Administration, Division of Labeling and Nonprescription Drug Compliance (HFD-310), 5600 Fishers Lane, Rockville, MD 20857, Attention: Kevin M. Budich, Compliance Officer. If necessary, you may contact Mr. Budich by telephone at 1-301-594-1065.

Sincerely yours,

Bradford W. Williams
Director
Division of Labeling and Nonprescription
Drug Compliance
Office of Compliance
Center for Drug Evaluation and Research