DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

WARNING LETTER

Food and Drug Administration
Rockville MD 20857

MAR 3 1998

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

Ref: 8-HFD-312-01

Dear Mr.

This is in reference to "4 WAY Fast Acting" nasal spray marketed by your firm. The product is labeled as a decongestant and antihistamine and contains phenylephrine hydrochloride 0.5%, pyrilamine maleate 0.2%, and naphazoline hydrochloride 0.05% as the active ingredients.

As a nasal decongestant and antihistamine, the product is subject to final regulations covering OTC nasal decongestant and antihistamine drug products found in Title 21 Code of Federal Regulations (21 CFR) part 341. Although pyrilamine maleate is acceptable for oral dosage as an antihistamine under the final regulations (21 CFR 341.12), the ingredient is not acceptable as a topical antihistamine for use in a nasal spray. Therefore, we consider the product to be a "new drug" (section 201(p) of the Federal Food, Drug, and Cosmetic Act) which may not be legally marketed in the United States without an approved New Drug Application (section 505). The product is also misbranded (section 502 of the Act) because the directions for use do not meet the regulations.

In addition to the violations noted above, the product is misbranded (section 502 of the Act) for failure to comply with the final regulations covering topical nasal decongestant drug products under 21 CFR 341. The labeling fails to bear the complete warnings for topical nasal decongestants required by 21 CFR 341.80(c)(2)(iii)(A). The warning statement required by 21 CFR 341.80(c)(2)(i)(A) needs to be in bold type.

The above list of violations is 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: Robert A. Eshelman, Compliance Officer.

Sincerely yours,

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