



MAY 26 1998

**TRANSMITTED BY FACSIMILE**

Thomas E. Costa  
Vice President and Counsel  
U.S. Pharmaceutical Group  
Bristol-Myers Squibb  
P.O. Box 4500  
Princeton, NJ 08543-4500

Re: ANDA 74-061  
Naproxen Delayed Release Tablets  
MACMIS ID#6284

Dear Mr. Costa:

This letter concerns promotional materials for Bristol-Myers Squibb's (BMS) product naproxen delayed release tablets. Based on materials the Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed as part of its monitoring program, it appears that BMS was promoting this drug in interstate commerce prior to its approval for marketing by the Food and Drug Administration. The promotion of drugs prior to their approval for marketing is in violation of the Federal Food, Drug, and Cosmetic Act (Act) and regulations promulgated thereunder.

Specifically, BMS disseminated a letter introducing the availability of naproxen delayed release tablets dated January 16, 1998. This letter was accompanied with an informational packet that made significant representations concerning the efficacy, safety, and rating of this product in comparison to the branded product. However, BMS did not receive approval for marketing until February 18, 1998. Therefore, these representations constitute pre-approval promotion and are in violation of the Act.

BMS should acknowledge receipt of this letter and its plans to discontinue similar violative promotional activities by June 9, 1998. BMS should direct its response to the undersigned at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD, 20857. DDMAC reminds BMS that only written communications are considered official.

Mr. Thomas E. Costa  
Bristol-Myers Squibb  
ANDA 74-061

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In all future correspondence regarding this matter, please refer to MACMIS ID #6284, in addition to the NDA number.

Sincerely,

Stephen W. Sherman, JD, MBA  
Regulatory Review Officer  
Division of Drug Marketing,  
Advertising and Communications