DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

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.

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