DEPARTMEN HEALTH & HUMAN SERVICES

Pu' alth Service

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Food and Drug Administration
Rockville MD 20857

MAY - 1 1998

TRANSMITTED VIA FACSIMILE

Thomas E. Costa
Vice President & Senior Counsel
Bristol-Myers Squibb Company
U.S. Pharmaceuticals
P.O. Box 4500
Princeton, NJ 08543-4500

Re: **NDA 19-898**
Pravachol (pravastatin sodium) Tablets
MACMIS ID # 6498

Dear Mr. Costa:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of promotional materials for Pravachol (pravastatin) that are in violation of the Federal Food, Drug and Cosmetic Act (Act) and the regulations promulgated thereunder. Specifically, DDMAC objects to two direct-to-consumer items: a newspaper advertisement (D3-B001-3-98) and a 90 second broadcast advertisement (#BMPL-8127), included in April 3, 1998 and April 21, 1998, FDA form 2253 submissions, respectively. A description of the objections is provided below.

Fair Balance

The broadcast advertisement is lacking in fair balance because the information related to the effectiveness of Pravachol is presented in greater scope, depth or detail than the information related to the risks associated with the use of Pravachol. The focus of this advertisement is weighted heavily on the advantages and/or positive messages of using Pravachol and does not provide a discussion of risks that is comparable in either scope or depth. In addition, the bolded warning information regarding the need to conduct liver function tests because of Pravachol's potential to cause liver "problems" is minimized. The phrase "Your doctor may do blood tests to check your liver function" does not clearly communicate that these tests are being conducted because the use of Pravachol itself might cause liver problems and not just that pre-existing liver problems are a contraindication to the use of Pravachol.

Indication Statement

Both advertisements are misleading because they do not adequately communicate the complete indication for the use of Pravachol from the INDICATIONS AND USAGE section of the approved product labeling. In the broadcast advertisement, the statement "Pravachol with diet and exercise has been prescribed for millions", presented as a claim about the number of people who have taken the product, is not adequate to convey the limitation that Pravachol should be used in patients only after an attempt at diet and other non-pharmacological measures alone has been inadequate, and that Pravachol should be used in addition to these measures.

In the newspaper advertisement, the headline "Pravachol is the only drug of its kind proven to reduce the risk of heart attack by 24% and stroke or mini-stroke by 26%" does not include the limitations to the use of Pravachol nor the qualifications for the population in which these benefits were proven. Notwithstanding the fact that these disclosures are made in the running text following the headline, untrue or misleading information in any part of the advertisement is not corrected by inclusion of true information elsewhere in the advertisement.

Prescription Drug Status

The broadcast advertisement is misleading because Bristol-Myers Squibb (BMS) does not communicate that Pravachol is a prescription drug product, only available upon a determination of need by one's physician. This omission impacts upon the ability of consumers to comprehend the risks associated with the use of Pravachol and therefore, BMS should clearly disclose this information.

BMS should immediately discontinue the use of the newspaper advertisement and other promotional materials that contain the same or similar representations for Pravachol discussed above. BMS should submit a written response to DDMAC on or before May 10, 1998, confirming that BMS has discontinued the use of such materials. BMS should also provide confirmation that they have discontinued the airing of the broadcast advertisement as of April 30, 1998, as represented by BMS in a teleconference with DDMAC on May 1, 1998.

If BMS has any questions or comments, please contact the undersigned by facsimile at (301) 594-6771, or in writing at DDMAC, HFD-40, Room 17B-20, 5600 Fishers Lane, Rockville MD 20857.

In all correspondence related to this matter, please refer to MACMIS ID #6498 in addition to the NDA number. DDMAC reminds BMS that only written communications are considered official.

Sincerely,

Jayne E. Peterson, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising, and Communications