



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NOV 26 1997

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 # 5679

Dear Mr. Costa:

The Food and Drug Administration is in receipt of information alleging that Bristol-Myers Squibb (BMS) representatives in the New York (Hyde Park) area are engaged in promotional activities that entail, among other things, the affixation of stickers to sample boxes and to candy. The stickers bear the words-- "Pravachol--The Real Lifesaver." This claim does not reflect the limitations of the approved indication for Pravachol and is, therefore, misleading, in violation of the Federal Food, Drug, and Cosmetic Act and the implementing regulations. In addition, our records do not reveal that the sticker, sample box, or candy were submitted to the Division of Drug Marketing, Advertising and Communications (DDMAC), in accordance with the post-marketing reporting requirements (21 CFR \$314.81).

BMS should immediately discontinue the dissemination of these and all other violative advertising or labeling pieces. Further, DDMAC requests that BMS submit a written response to DDMAC by December 12, 1997. This response should include the following:

- A list of all materials that have been discontinued;
- BMS' plan to comply with DDMAC's request;

If BMS has further comments, please contact the undersigned by facsimile at (301) 594-6771, or at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm 17B-20, 5600 Fishers Lane, Rockville, MD 20857.

Thomas E. Costa
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In all future correspondence regarding this launch, please refer to MACMIS ID #5679 in addition to the NDA number.

Sincerely,

Anne M. Reb, NP
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications