



TRANSMITTED BY FACSIMILE

Philomena A. McArthur
Associate Director, Regulatory Services
Worldwide Medicines Group
Bristol-Myers Squibb Company
P.O. Box 4500
Princeton, NJ 08543-4500

RE: NDA# 19-898
Pravachol (pravastatin sodium) Tablets
MACMIS ID#: 10534

Dear Ms. McArthur:

This letter concerns Bristol-Myers Squibb's (BMS) direct-to-consumer print advertisement for Pravachol (pravastatin sodium) Tablets, which appeared in the December 3, 2001, issue of *Newsweek*. The Division of Drug Marketing, Advertising, and Communications (DDMAC) has reviewed this magazine advertisement as part of its routine monitoring and surveillance program. DDMAC has concluded that BMS' advertisement is misleading in violation of the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations for the following reasons.

Misleading Safety Claim

- **“SAFETY: Pravachol was no more likely to cause side effects than a placebo (sugar pill) in landmark clinical studies (See important safety information below).”**

The safety claim that Pravachol “is no more likely to cause side effects than a placebo” (accompanied by the “SAFETY” headline) is misleading. This strong safety claim minimizes the potential risks associated with use of Pravachol (particularly liver problems and rhabdomyolysis or muscle disintegration). Furthermore, this prominently presented safety claim is not mitigated by the fair balance paragraph presented in the ad.

Unsubstantiated Claim

- **“EXPERIENCE: Pravachol has been trusted by doctors for more than 10 years.....”**

This claim is unsubstantiated and therefore misleading because BMS has not provided evidence demonstrating that doctors “trust” Pravachol.

Failure to Submit Post-Marketing Reports

Although this advertisement was disseminated in the December 3, 2001, issue of *Newsweek*, you have failed to submit it at the time of initial publication as required under the post-marketing reporting requirements (21 CFR 314.81(b)(3)(i)).

BMS should immediately discontinue this and all other promotional materials and activities for Pravachol that contain the same or similar presentations. We request that BMS respond in writing with its intent to discontinue such use. We should receive your written response no later than December 17, 2001. This response should list similarly violative materials with a description of the method for discontinuation and the discontinuation date.

Your response should be directed to Catherine A. Miller MT(ASCP) by facsimile at (301) 594-6771, or in writing at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications HFD-42, Rm. 17-B-20, 5600 Fishers Lane, Rockville, Maryland 20857.

In all future correspondence on this matter, please refer to MACMIS ID# 10534 as well as the NDA number. DDMAC reminds you that only written communications are considered official.

Sincerely,

{See appended electronic signature page}

Joan Hankin, JD
Consumer Promotion Analyst
Division of Drug Marketing,
Advertising, and Communications

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Joan Hankin
12/3/01 01:10:04 PM

HIGH CHOLESTEROL ISN'T JUST A NUMBER. IT'S A WARNING.

THREE REASONS TO ASK HOW PRAVACHOL CAN HELP PROTECT YOUR HEART.

1. PROOF: Pravachol, along with diet, is the only cholesterol-lowering drug proven to help prevent both first and second heart attacks in people with high cholesterol or heart disease when diet and exercise are not enough.

2. SAFETY: Pravachol was no more likely to cause side effects than a placebo (sugar pill) in landmark clinical studies. (See important safety information below.)

3. EXPERIENCE: Pravachol has been trusted by doctors for more than 10 years and prescribed more than 72 million times.


IMPORTANT SAFETY INFORMATION: Pravachol (pravastatin sodium), a prescription drug, is not for everyone, including women who are pregnant or nursing or may become pregnant, or people with liver problems. And because serious side effects can result, tell your doctor about any unexplained muscle pain or weakness you experience while on Pravachol, and about any other medications you are taking. Your doctor may do blood tests to check for liver problems. Some mild side effects, such as slight rash or stomach upset, occur in 2-4% of patients.

Ask your doctor to tell you more about high cholesterol, the risk of heart attack, and if Pravachol is right for you.

PRAVACHOL®
pravastatin sodium 40 mg
tablets

Please see important
information on adjacent page.

1-877-PRAVA-CALL

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D3-K089
www.pravachol.com