DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP 22 1997

Ellen R. Westrick
Senior Director, Office of Medical/Legal
Merck & Co., Inc.
P.O. Box 4, WP37B-113
West Point, Pennsylvania 19486

Re: **NDA 19-766**
Zocor (simvastatin)
MACMIS ID #5832

Dear Ms. Westrick:

Reference is made to Merck & Co. Inc.'s (Merck) September 5, 1997, form FDA 2253 submission for Zocor. The submission includes the following:

. 199705258 Zocor television (TV) commercial

The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed this broadcast advertisement and has determined that it is misleading in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations for the following reasons:

Communication of Risk Information

The broadcast advertisement is misleading because Merck fails to adequately present the risk information for Zocor. The risk information disclosed is not presented in a manner that is reasonably comparable to the presentation of efficacy information. The drug benefits information is presented twice in a clear manner with a relatively non-distracting visual background of a prescription bottle and Zocor tablets. In contrast, the required information relating to the major side effects and contraindications is presented in a less prominent manner with the announcer reading this information against a visual background of busy graphic presentations. In addition, the contraindications and warning information is presented in a confusing manner by including them in the same sentence as the

indication information. This presentation makes it difficult for consumers to fully comprehend the important risk information for Zocor.

The bolded warning regarding myopathy and rhabdomyolysis is not conveyed in a manner consistent with the seriousness of these side effects. The TV ad states, "Because side effects can result, tell your doctor about any medicines you are taking or any muscle pain or weakness you experience while on Zocor." The potential seriousness of the warning that may result in discontinuation of therapy; i.e. muscle disease, renal failure, is not clearly communicated.

In addition, the bolded warning regarding the incidence of elevated transaminase levels associated with Zocor and the need to monitor liver function tests is minimized. The ad states, "Your doctor may perform blood tests to check your liver." This phrasing does not clearly communicate the importance of the risk information, given that active liver disease or unexplained liver enzyme elevations are contraindications to the use of Zocor, and thus, could result in discontinuation of the medicine.

Communication of Indication

The TV ad is also misleading because it does not accurately communicate the indication for Zocor. Merck states, "Zocor is a prescription medicine when diet and exercise are inadequate." Merck fails to communicate that Zocor should be used "in addition to a diet restricted in saturated fat and cholesterol when the response to diet and other nonpharmacological measures alone has been inadequate," as stated in the approved product labeling. DDMAC has previously commented to Merck on this issue. For example, DDMAC refers you to its December 1, 1995, letter of comments for Zocor.

Adequate Provision

The Zocor TV advertisement does not adequately provide for the dissemination of the approved package labeling, or "adequate provision." For example, in this ad, the disclosure that directs the viewer to a doctor or pharmacist for additional product information does not adequately accomplish this communication. The vague phrasing, "Aren't there enough reasons in your life to ask your doctor about Zocor?" focuses on the potential benefits, rather than on the risks, or on the availability of more complete product information. This phrasing undermines the purpose of the communication, i.e., to let the consumer know that there is

additional product information they can get from different sources.

DDMAC requests that Merck immediately discontinue the television ad as well as any other promotional materials that contain similar themes. Please note that DDMAC is continuing to review other aspects of this promotional campaign.

DDMAC requests that Merck submit a written response to this letter no later than September 26, 1997. This response should include the following:

- A list of all materials and television ad placements that have been discontinued; and,
- Merck's plan to comply with DDMAC's request.

If Merck has further comments or issues, please contact me at the Food and Drug Administration, Division of Drug Marketing, Advertising and Communications, HFD-40, Rm. 17B-20, 5600 Fishers Lane, Rockville, MD 20857. In all future correspondence related to this matter, please refer to MACMIS ID #5832 and the NDA number.

Sincerely,

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