DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

JAN 26 1998

TRANSMITTED VIA FACSIMILE

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

RE: NDA# 19-766 Zocor
MACMIS ID # 6235

Dear Ms. Westrick:

Reference is made to Merck & Co. Inc.'s (Merck) November 14, 1997, form FDA 2253 submission of a detail aid for Zocor- New indication card #975910(2). DDMAC has reviewed this material and has determined that it is misleading in violation of the Federal Food, Drug, and Cosmetic Act for the following reasons:

The detail aid is misleading because the risk information on the front side of the card is not presented in a manner that is reasonably comparable to the presentation of efficacy information. The warning regarding myopathy and rhabdomyolysis is presented in small type at the bottom of the card against a dark background. In contrast, the efficacy information is presented in larger typesize against a prominent white background with colored bars highlighting the main efficacy claims.

DDMAC provided comments to Merck on this issue in our November 4, 1997, letter of comments. In that letter, DDMAC stated that the presentation of the risk information on the front side of the detail aid would not be reasonably comparable to the presentation of the efficacy information and recommended that the prominence of the information be increased. In addition, the detail aid lacks fair balance because it fails to present the most common adverse events for Zocor.

DDMAC requests that Merck immediately discontinue the dissemination and use of the detail aid and any other promotional materials that contain similar themes. DDMAC requests that Merck submit a written response to this letter no later than February 9, 1998. This response should include the following:

- A list of all materials that have been discontinued;
- 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 #6235 and the NDA number.

Sincerely,

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