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**TRANSMITTED VIA FACSIMILE**

Ellen R. Westrick  
Senior Director  
Office of Medical/Legal  
Merck & Co., Inc.  
P.O. Box 4, WP37C-116  
West Point, Pennsylvania 19846

**RE: NDA 19-766**  
Zocor (simvastatin)  
MACMIS ID #5444

Dear Ms. Westrick:

Reference is made to Merck's flash cards #974138(1)-05-ZOC and 971738-02-ZOC for Zocor. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these flash cards and finds them in violation of the Federal Food, Drug, and Cosmetic Act and the applicable regulations.

Specifically, DDMAC objects to the following claims and representations:

**974138(1)-05-ZOC**

- The comparison of percent of patients brought to LDL-C goal at 52 weeks between Zocor and Lipitor is misleading because it misrepresents the design of the study. Specifically, the dose of the two agents were increased only one time and one dosage strength (from 10 mg to 20 mg), at 16 weeks. Therefore, this is not a true titrate-to-goal study because this study did not cover the full dose range of either statin. As such, it does not account for the apparent differences in effectiveness that might have been negated by using higher doses of each agent.
- The statement "At the starting dose, neither product achieved NCEP goal for a majority of patients" is misleading because it misrepresents the goal and results of the study. Specifically, at 16 weeks, the percentage of patients who achieved the study goal was statistically significantly higher for those receiving Lipitor compared to those who received Zocor.

- The claim that "Zocor has been proven to reduce LDL-C to NCEP goal in a majority of patients" juxtapositioned with the graphic showing that 92% of patients require a  $\leq 40\%$  reduction is misleading because it overstates Zocor's efficacy by implying that Zocor brings most of the 92% of patients to goal. It is DDMAC's understanding that for those patients who require drug therapy, Zocor brings about 51% to their needed goals.

**971738-02-ZOC**

- This detail piece contains a table that presents comparisons of Lipitor and Zocor. These comparisons are misleading because they imply that Zocor is safer and more effective than Lipitor, without adequate supporting evidence.

DDMAC acknowledges Merck's May 30 and June 9, 1997, letters that state that Merck has discontinued the use of these and similar promotional pieces. Therefore, no further action is requested at this time and DDMAC considers this matter closed.

If Merck 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 #5444, in addition to the NDA number.

Sincerely,



Leah Palmer, Pharm.D.  
Branch Chief  
Division of Drug Marketing,  
Advertising and Communications