DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

OCT 20 1997

Ellen R. Westrick
Senior Director
Office of Medical/Legal
Merck & Co., Inc.
Sumneytown Pike
West Point, PA 19486

RE: NDA#20-386/20-387
Cozaar (losartan potassium) tablets and
Hyzaar (losartan potassium-hydrochlorothiazide) tablets
MACMIS ID #5910

Dear Ms. Westrick:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC), has become aware of promotional materials for Cozaar (losartan potassium) tablets and Hyzaar (losartan potassium-hydrochlorothiazide) tablets by Merck & Co., Inc. (Merck) that violate the Federal Food, Drug, and Cosmetic Act and its regulations. Reference is made to the following materials submitted under cover of Form FDA 2253: journal ad (972067), and leaflets (975462, 975325, and 975306). DDMAC has reviewed these promotional materials and determined that they promote Cozaar and Hyzaar in a manner which is considered false and/or misleading because they are lacking in fair balance, or otherwise misleading.

Promotional materials must present information about the risks associated with the use of the drug in a manner reasonably comparable to that of claims concerning the drug's efficacy. The above referenced promotional materials fail to present any information relating to the most common adverse events associated with Cozaar and Hyzaar. The approved product labeling for Cozaar and Hyzaar list side effects associated with the use of these drugs, several of which occur at higher rates in patients receiving Cozaar or Hyzaar versus placebo. Without qualification, DDMAC considers the claims "excellent tolerability" and "overall incidence of adverse effects comparable to placebo" to be false and/or misleading because they minimize the importance of the side effects that do occur with the use of these drugs. In addition, the journal ad fails to present risk information concerning a serious adverse event, angioedema, reported with the use of losartan. Further, prominence in presentation of the risk information in these promotional materials is not comparable to presentation of the claims of efficacy. Therefore, these promotional materials are lacking in fair balance, or otherwise misleading

because they misrepresent the safety profiles of Cozaar and Hyzaar, and do not present risk information with a prominence comparable to efficacy claims.

Merck should immediately cease distribution of these and other similar promotional materials for Cozaar and Hyzaar that contain the same or similar claims or presentations. Merck should submit a written response to DDMAC on or before November 3, 1997, describing its intent and plans to comply with the above.

Merck should direct its response to 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. DDMAC reminds Merck that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #5910 in addition to the NDA numbers.

Sincerely,

Janet Norden, MSN, RN
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications