DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

OCT 27 1997

Cora Collins
U.S. Regulatory Affairs, Marketed Products
Hoechst Marion Roussel, Inc.
10236 Marion Park Drive
P.O. Box 9627
Kansas City, MO 64134-0627

RE: **NDA# 19-901**
Altace (ramipril) capsules
MACMIS ID# 5945

Dear Ms. Collins:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of promotional materials for Altace (ramipril) capsules by Hoechst Marion Roussel, Inc. (HMR) that violate the Federal Food, Drug and Cosmetic Act and its regulations. Reference is made to the following promotional materials submitted under cover of Form FDA 2253: box (97259901/1870M7) and booklet (97210603/1249H7). DDMAC has reviewed these materials and has determined that they promote Altace 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. With the exception of a disclaimer for the risk of excessive hypotension in patients with congestive heart failure, the promotional box listed above fails to present any other information relating to the most common adverse events, warnings or precautions associated with Altace. The approved product labeling contains a prominent boxed warning for use in pregnancy, as well as other warnings, precautions and serious adverse reactions associated with the use of Altace. Since Altace has significant risks associated with its use, this promotional material is lacking in fair balance, or otherwise misleading because it fails to address these risks.

In addition, in the promotional box, HMR claims that Altace is comparable in cost to other ACE inhibitors and "packed with patient value to enhance compliance," without disclosing the source of such a claim. Claims for cost comparisons should include the source and date of the cost information and a statement that the prices may not represent actual savings by consumers or pharmacies. Further, once-daily dosing and competitive pricing have not been demonstrated

to adequately support a claim of enhanced patient compliance. Therefore, DDMAC considers these claims to be false and/or misleading.

In the booklet, HMR presents the most common adverse events associated with the use of Altace for the treatment of hypertension. However, HMR fails to present other important risk information, including the boxed warning for use in pregnancy and the serious adverse event, angioedema, that has been reported with the use of Altace. Therefore, this booklet is lacking in fair balance, or otherwise misleading.

HMR should immediately cease distribution of these and other similar promotional materials for Altace that contain the same or similar claims or presentations. HMR should submit a written response to DDMAC on or before November 10, 1997, describing its intent and plans to comply with the above.

HMR 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 HMR that only written communications are considered official.

In all future correspondence regarding this particular matter please refer to MACMIS ID #5945 in addition to the NDA number.

Sincerely,

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