DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

AUG 18 1997

TRANSMITTED VIA FACSIMILE

Carl Schlotfeldt
Associate Director
Drug Regulatory Affairs
Pharmaceutical Division
Novartis Pharmaceuticals Corporation
556 Morris Avenue
Summit, NJ 07901-1398

RE: **NDA#** 20-364
Lotrel (amlodipine besylate/benazepril HCl) Capsules
MACMIS ID# 5729

Dear Mr. Schlotfeldt:

Reference is made to promotional materials submitted by Novartis Pharmaceuticals Corporation (Novartis) under cover of FDA Form 2253, dated July 7, 1997. The Division of Drug Marketing, Advertising and Communications (DDMAC) has reviewed these materials for Lotrel and has determined that they promote Lotrel in a manner in violation of the Federal Food, Drug and Cosmetic Act and its regulations. Specifically we refer to a pharmacy educator slide program [LTR-2002], a slide brochure [LTR-3001], and a Dear Pharmacy Educator letter used to promote Lotrel which are 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 slide program and brochure fail to present any information relating to the most common adverse events, warnings, or precautions associated with Lotrel. The approved product labeling contains a prominent boxed warning for use in pregnancy, as well as other warnings, precautions and adverse reactions associated with the use of Lotrel. Since Lotrel has significant risks associated with its use, these promotional materials are lacking in fair balance, or otherwise misleading because they fail to address these risks.

In addition, the Dear Pharmacy Educator letter provides risk information in a small type size footnote at the bottom of the letter. Presentation of risk information in this manner is not sufficient to provide prominence and readability comparable with the presentation of information relating to effectiveness of the drug in the body of the letter. Therefore, this promotional piece is lacking in fair balance, or otherwise misleading.

Novartis should immediately cease distribution of these and other similar promotional materials for Lotrel that contain the same or similar claims or presentations. Novartis should submit a written response to DDMAC on or before September 2, 1997, describing its intent and plans to comply with the above.

Novartis 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 Novartis that only written communications are considered official.

In all future correspondence regarding this particular matter please refer to MACMIS ID #5729 in addition to the NDA number.

Sincerely,

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