DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

**TRANSMITTED VIA FACSIMILE**

FEB 11 1998

Kevin McKenna, Ph.D.
Manager, Marketed Products Group
Drug Regulatory Affairs Department
Zeneca Pharmaceuticals
1800 Concord Pike
Wilmington, DE 19850

RE: **NDA 19-777**
Zestril (lisinopril)
MACMIS ID # 6224

Dear Dr. McKenna:

As part of our routine monitoring and surveillance activities, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has received information that Zeneca Pharmaceuticals (Zeneca) is promoting Zestril (lisinopril) in violation of the Federal Food, Drug and Cosmetic Act (Act) and its implementing regulations. Specifically, we refer to a direct-to-consumer (DTC) letter, funded by Zeneca and disseminated by Walgreens (see Attachment). DDMAC has reviewed this letter and has determined that it is in violation of the Act for the following reasons:

In its DTC letter, Zeneca does not make any claims or representations about the use of Zestril. For this reason, this DTC letter could represent "reminder labeling." However, reminder labeling is not permitted for prescription drugs whose approved product labeling contains a boxed warning relating to a serious adverse event associated with the use of the drug. Since the approved product labeling for Zestril contains a boxed warning concerning the risk of fetal injury and death when used during pregnancy, this DTC letter constitutes promotional labeling. Therefore, DDMAC considers Zeneca's DTC letter to be in violation of the Act because it fails to provide the consumer with information relating to the effectiveness, side effects, and contraindications associated with Zestril's use, and it is not accompanied by the approved product labeling for Zestril.

Furthermore, in this DTC letter, Zeneca fails to present the established name for Zestril (i.e., lisinopril) which is in violation of the Act and its implementing regulations. In promotional materials, the established name must accompany, and be placed in direct conjunction with, the proprietary name.

Finally, it appears that this labeling piece was not submitted to the FDA by Zeneca pursuant to

the postmarketing reporting requirements for promotional labeling and advertising, 21 CFR 314.81(b)(3).

Zeneca should immediately cease distribution of this DTC letter and other similar promotional materials for Zestril that contain the same or similar claims or presentations. Zeneca should submit a written response to DDMAC on or before February 26, 1998, describing its intent and plans to comply with the above.

Zeneca 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, Maryland 20857. DDMAC reminds Zeneca that only written communications are considered official.

In all correspondence regarding this particular matter, please refer to MACMIS ID #6224, in addition to the NDA number.

Sincerely,

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

Attachment