DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FOI

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

FEB 4 2000

Mr. Douglas N. Dobak
Quality Liason Leader
AstraZeneca L.P.
725 Chesterbrook Blvd.
Wayne, PA 19087

RE: NDA #19-810 Prilosec (omeprazole) Delayed-Release Capsules
NDA #20-916
MACMIS ID 8694

Dear Mr. Dobak:

As part of its routine monitoring and surveillance program, the Division of Drug Marketing, Advertising and Communications (DDMAC) has become aware of a direct-to-consumer (DTC) broadcast advertisement for Prilosec (omeprazole) Delayed-Release Capsules that is in violation of the Federal Food, Drug, and Cosmetic Act and applicable regulations. This DTC broadcast advertisement, submitted to the Agency on Form FDA 2253, is identified as #161827.

Your broadcast advertisement #161827 for Prilosec contains audio representations and suggestions about Prilosec yet fails to include information relating to Prilosec's major side effects and contraindications. In addition, in the absence of a brief summary, the advertisement fails to make adequate provision for disseminating the approved product labeling.

Broadcast advertisements for prescription drugs that include representations or suggestions relating to the advertised drug product must include information relating to the major side effects and contraindications of the advertised drug. In addition, unless adequate provision is made for disseminating the approved product labeling in connection with the broadcast presentation, such advertisements must contain a brief summary of all necessary information related to side effects and contraindications.

DDMAC requests that AstraZeneca immediately cease using this advertisement and all other promotional materials for Prilosec that contain the same or similar presentations. AstraZeneca should submit a written response to DDMAC, on or before February 17, 2000, describing its intent to comply with the above. Your written response should include a list of promotional materials that were discontinued, and the discontinuation date.

AstraZeneca should direct its response to the undersigned by facsimile at (301) 594-6759 or at the Food and Drug Administration, Division of Drug Marketing, Advertising, and Communications, HFD-42, Rm. 17B-04, 5600 Fishers Lane, Rockville, MD 20857. DDMAC reminds AstraZeneca that only written communications are considered official.

In all future correspondence regarding this particular matter, please refer to MACMIS ID #8694 in addition to the NDA number.

Sincerely,

/S/

Patricia Kuker Staub, R.Ph., J.D.
Regulatory Review Officer
Division of Drug Marketing,
Advertising and Communications