



**TRANSMITTED VIA FACSIMILE**

JAN 3 2001

Mr. John Markow  
Director, Promotional Regulatory Affairs  
AstraZeneca LP  
725 Chesterbrook Blvd.  
Wayne, PA 19087-5677

**RE: NDA #19-810 Prilosec (omeprazole) Delayed-Release Capsules  
MACMIS ID #9612**

Dear Mr. Markow:

The Division of Drug Marketing, Advertising, and Communications (DDMAC) has determined that AstraZeneca LP (AstraZeneca) has disseminated a broadcast (TV) advertisement for Prilosec (omeprazole) Delayed-Release Capsules that is in violation of the Federal Food, Drug, and Cosmetic Act. Specifically, DDMAC considers this broadcast advertisement to be a product-specific advertisement because it discusses acid-reflux disease in conjunction with "the purple pill." AstraZeneca manufactures Prilosec, which is the only purple pill that treats heartburn due to acid-reflux disease. Thus, the advertisement identifies the specific product without providing adequate information on Prilosec's approved indication and usage. Furthermore, the advertisement lacks fair balance.

In order to address these objections, DDMAC requests that AstraZeneca immediately discontinue the use of this advertisement, and all other promotional materials for Prilosec that contain the same or similar violations. We also request that you provide to DDMAC, in writing, your intent to comply with our request by January 15, 2001. This response should include a list of all violative promotional materials, and AstraZeneca's method for discontinuing their use.

If you have any questions, you should direct them to the undersigned in writing or by facsimile at (301) 594-6759 or at the Food and Drug Administration, Division of Drug

John Markow  
AstraZeneca  
NDA 19-810  
MACMIS # 9612

Page 2

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 #9612 in addition to the NDA number.

Sincerely,

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