DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

TRANSMITTED VIA FACSIMILE

SEP 23 1999

Preeti Pinto, M.S., M.T. (ASCP)
Quality Assurance Liaison Leader
AstraZeneca, LP
725 Chesterbrook Blvd.
Wayne, PA 19087-1000

RE: NDA #19-834
Plendil (felodipine) extended-release tablets
MACMIS ID #8219

Dear Ms. Pinto:

As part of its routine monitoring program, the Division of Drug Marketing, Advertising, and Communications (DDMAC) has become aware of a promotional labeling piece for Plendil (felodipine) extended release tablets, disseminated by AstraZeneca, LP (Astra) that violates the Federal Food, Drug, and Cosmetic Act (Act) and its implementing regulations. Reference is made to a promotional card, identified as 158863, submitted under cover of Form FDA 2253. DDMAC has reviewed this promotional card and has determined that it promotes Plendil for unapproved uses, and lacks fair balance.

Unapproved uses

On this promotional card, Astra presents claims that imply that Plendil (felodipine) is indicated for reducing mortality and major cardiovascular events (fatal and nonfatal myocardial infarction, fatal and nonfatal stroke, and all other cardiovascular deaths) in hypertensive patients. For example:

- The consensus is clear: More vigorous treatment of hypertension can save lives
- Lowering blood pressure to and below 140 mm Hg systolic and 90 mm Hg diastolic reduced the risk of major cardiovascular events

However, Plendil (felodipine) is not indicated for these uses. The Indication and Usage section of the approved product labeling (PI) for Plendil (felodipine) states that "Plendil is indicated for the treatment of hypertension. Plendil may be used alone or concomitantly with other antihypertensive agents." Therefore, this card promotes Plendil for unapproved uses.

We note that Astra presents a disclaimer, in small size type at the bottom of the card that "The ability of calcium channel blockers to reduce morbidity or mortality has not been established." However, the inclusion of this disclaimer does not adequately correct the implications made by claims presented on this promotional card.

Lack of fair balance

Promotional materials must present information relating to contraindications, precautions, and side effects with a prominence and readability reasonably comparable to the presentation relating to the effectiveness of the drug. Claims promoting the effectiveness of Plendil are presented in large, bold letters. However, the risk information is presented in small sized type at the bottom of the card. This presentation is misleading because the risk information is not presented in a reasonably comparable manner.

In order to address these objections, Astra should immediately cease distribution of this card and other promotional materials for Plendil that contain the same or similar claims and presentations. Astra should provide a written response to DDMAC on or before October 7, 1999, describing its intent to comply with the above request. In its response to DDMAC, Astra should include a list of materials discontinued, and the date on which these materials were discontinued.

Astra 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 Astra that only written communications are considered official. In all correspondence regarding this particular matter, please refer to MACMIS ID #8219 in addition to the NDA number.

Sincerely,

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