DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-834/S-017

AstraZeneca
Attention: Ms. Cindy M. Lancaster
1800 Concord Pike
PO Box 8355
Wilmington, DE 19803-8355

Dear Ms. Lancaster:

Please refer to your supplemental new drug application dated December 20, 2000 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plendil (felodipine) Tablets.

We acknowledge receipt of your submission dated December 14, 2001.

This "Changes Being Effected" supplemental new drug application provides for final printed labeling revised by the additions of *leukocytoclastic vasculitis* and *angioedema* to the **ADVERSE REACTIONS** section as part of post marketing safety surveillance. It also included changes in the **PRECAUTIONS, Carcinogenesis, Mutagenesis, Impairment of Fertility** and **Pregnancy** subsections requested in the Agency's August 28, 2000 letter. In addition, AstraZeneca's identity change was included as well as some editorial changes.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert included in your electronic submission of December 14, 2001). Accordingly, the supplemental application is approved effective on the date of this letter.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Denise Hinton, BSN, RN Regulatory Health Project Manager (301) 594-5312.

Sincerely,

{See appended electronic signature page
Douglas C.Throckmorton M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Doug Throckmorton

5/22/02 03:51:10 PM