CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number: NDA 19834/S002

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administratio
Rockville MD 20857

NDA 19-834/S-002

SEP 22 1994

Astra/Merck Group of Merck & Co., Inc.
Attention: Elliott T. Berger, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Berger:

Please refer to your July 28, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Plendil (felodipine) Tablets.

We also acknowledge receipt of your amendment dated September 2, 1994.

The supplemental application provides for a new 2.5 mg dosage strength and final printed labeling revised to reflect this change as well as a decrease in the maximum recommended dose from 20 mg to 10 mg.

We have completed the review of this supplemental application and it is approved.

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

Sincerely yours,

/S/ 9/22/94

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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APPLICATION NUMBER: NDA 19834/S002

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Public Health Service

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JUL 27 1994

Astra/Merck Group of Merck & Co., Inc.
Attention: Elliott T. Berger, Ph.D.
725 Chesterbrook Blvd.
Wayne, PA 19087-5677

Dear Dr. Berger:

Please refer to your July 28, 1993 supplemental new drug application submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for Plendil (felodipine) Tablets.

The supplemental application provides for a new dosage strength, 2.5 mg.

We have completed the review of this supplemental application as submitted with draft labeling. Before this supplement may be approved, however, it will be necessary for you to submit final printed labeling. The labeling should be identical in content to the enclosed marked-up draft. In addition, all previous revisions as reflected in the most recently approved package insert must be included. To facilitate review of your submission, please provide a highlighted or marked-up copy that shows the changes that are being made.

If additional information relating to the safety or effectiveness of this drug becomes available before we receive the final printed labeling, revision of that labeling may be required.

Please submit fifteen copies of the printed labeling ten of which are individually mounted on heavy weight paper or similar material.

Within 10 days after the date of this letter, you are required to amend this supplemental application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of such action, FDA may take action to withdraw this supplemental application.

Should you have any questions, please contact:

Mr. David Roeder
Consumer Safety Officer
Telephone: (301) 594-5300

Sincerely yours,

/S/ 7/27/94

Raymond J. Lipicky, M.D.
Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosure