

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**Approval Package for:**

***APPLICATION NUMBER:***

**19-834/S006**

***Trade Name:*** Plendil

***Generic Name:*** Felodipine

***Sponsor:*** Astra Merck

***Approval Date:*** July 3, 1996

***Indications:*** The treatment of hypertension.

# CENTER FOR DRUG EVALUATION AND RESEARCH

**APPLICATION NUMBER:**

**19-834/S006**

## CONTENTS

### Reviews / Information Included in this NDA Review.

<b>Approval Letter</b>	<b>X</b>
<b>Approvable Letter</b>	
<b>Labeling</b>	
<b>Medical Review(s)</b>	
<b>Chemistry Review(s)</b>	<b>X</b>
<b>Pharmacology Review(s)</b>	
<b>Statistical Review(s)</b>	
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RESEARCH**

***APPLICATION NUMBER:***

**19-834/S006**

**APPROVAL LETTER**

JUL \_ 3 1996

NDA 19-834/S-006

Astra Merck  
Attention: Daniel J. Cushing, Ph.D.  
725 Chesterbrook Blvd.  
Wayne, PA 19087-5677

Dear Dr. Cushing:

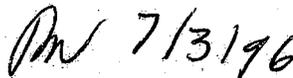
Please refer to your May 10, 1996 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PLENDIL (felodipine) 2.5 mg, 5 mg and 10 mg Extended-Release Tablets.

The supplemental application provides for the updated particle size specification for the \_\_\_\_\_

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,



Robert J. Wolters, Ph.D.  
Chemistry Team Leader, DNDC-1  
Division of Cardio-Renal Drug Products (HFD-110)  
Office of Drug Evaluation 1  
Center for Drug Evaluation and Research

cc:

Original NDA

DISTRICT OFFICE

HFD-110

HFD-110/Project Manager

HFD-80

HFD-810/CHOiberg

HFD-110/RMittal/6/28/96

kc/6/28/96

Approval Date: July 25, 1991

APPROVAL

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

***APPLICATION NUMBER:***

**19-834/S006**

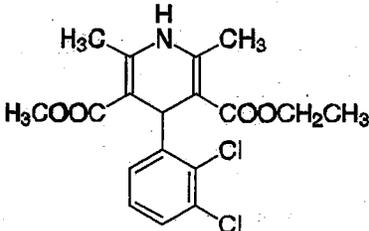
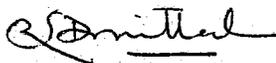
**CHEMISTRY REVIEW(S)**

JUL 3 1996

NDA 19-834

PLENDIL

ASTRA-MERCK

<b>CHEMIST'S REVIEW</b>		<b>1. ORGANIZATION</b> HFD - 110	<b>2. NDA Number</b> 19-834
<b>3. Name and Address of Applicant (City &amp; State)</b> Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		<b>4. Supplement(s) Number/Date</b> SCS-006 05-10-96	
<b>5. Drug Name</b> PLENDIL	<b>6. Nonproprietary Name</b> Felodipine		<b>8. Amendments &amp; Other (reports, etc) - Dates</b>
<b>7. Supplement provides for:</b> Update of the particle size specification for the			
<b>9. Pharmacological Category</b> Hypertension	<b>10. How Dispensed</b> <input checked="" type="checkbox"/> / RX <input type="checkbox"/> / OTC		<b>11. Related IND(s)/ NDA(s)/DMF(s)</b>
<b>12. Dosage Form(s)</b> Tablets	<b>13. Potency(ies)</b> 2.5 mg, 5 mg, and 10 mg		
<b>14. Chemical Name and Structure</b> (±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate. 			<b>15. Records/Reports</b> <b>Current</b> <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No <b>Reviewed</b> <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No
<b>16. Comments:</b> See review on following pages.			
<b>17. Conclusions and Recommendations:</b> Satisfactory and approval letter is being sent.			
<b>18. REVIEWER</b>			
<b>Name</b> Ramsharan D. Mittal	<b>Signature</b> 		<b>Date Completed</b> 06-28-96
<b>19. Distribution:</b> <input checked="" type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO			

*J. Mittal*  
7/1/96

1   Page(s) Withheld

§ 552(b)(4) Trade Secret / Confidential

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling