

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPLICATION NUMBER: NDA 19834/S002**

**CHEMISTRY REVIEW(S)**

NDA 19-834

PLENDIL

MERCCK

SEP 15 1994

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) Merck Research Laboratories Sumneytown Pike West Point, Pa 19486		4. Supplement(s) Number(s) Date(s) SE2-002 (AE)	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates  9-2-94
7. Supplnt amendment provide for:  Revised labeling for inclusion of a new dosage strength, 2.5 mg; as well as a revision under ADVERSE REACTIONS.			
9. Pharmacological Category Hypertension	10. How Dispensed <input checked="" type="checkbox"/> / RX <input type="checkbox"/> / OTC		11. Related IND(s) / NDA(s) / DMF(s)
12. Dosage Form(s) Tablets	13. Potency(ies) 2.5 mg, 5 mg and 10 mg		
14. Chemical Name and Structure  (±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate.		15. Records/Reports  Current <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No  Reviewed <input checked="" type="checkbox"/> / Yes <input type="checkbox"/> / No	
16. Comments:  Approval letter for this supplement is being sent by Dr. Lipicky.			
17. Conclusions and Recommendations:  Satisfactory.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <i>RSI</i>		Date Completed 09-14-94
19. Distribution: <input type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

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*RSI*  
y- 9-14-94

SEP 7 1993

DIVISION OF CARDIO-RENAL DRUG PRODUCT  
Review of Chemistry, Manufacturing, and Control.

NDA #: 19-834 CHEM. REVIEW #: 8 REVIEW DATE: 02-SEP-93

SUBMISSION TYPE DOCUMENT DATE CDER DATE ASSIGNED DATE

SUPPL SE2/S-002 28-JUL-93 02-AUG-93 03-AUG-93

NAME & ADDRESS OF SPONSOR

Merck Research Laboratories  
Sumneytown Pike  
West Point, Pa. 19486

DRUG PRODUCT NAME

Proprietary: PLENDIL<sup>®</sup>  
Nonproprietary/USAN: Felodipine  
INN/Other: Splendil, Modip (Europe)  
Code Name/#: H154/82 & MK0218  
Chem. Type/Ther. Class:

ANDA Suitability Petition/DESI/Patent Status: N/A

PHARMACOL. CATEGORY/INDICATION: Calcium Channel blocker / hypertension

DOSAGE FORM: Extended release film coated tablets

STRENGTH: 2.5 mg

ROUTE OF ADMINISTRATION: ORAL

DISPENSED: Rx

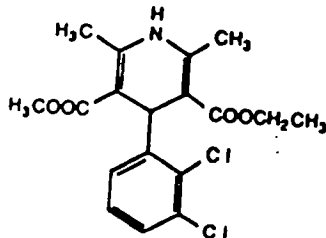
CHEMICAL NAME: (+)-Ethyl Methyl 4-(2-(2,3-dichlorophenyl)-1,4-dihydro-2,6-dimethyl-3,5-pyridine dicarboxylate.

CAS #: 72509-76-3

MOLECULAR FORMULA: C<sub>18</sub>H<sub>19</sub>Cl<sub>2</sub>NO<sub>4</sub>

MOLECULAR WEIGHT: 384.3

STRUCTURAL FORMULA:



**SUPPORTING DOCUMENTS:**

Original NDA 19-834 and amendments.

**RELATED DOCUMENTS (if applicable):**

None.

**CONSULTS:**

None at present.

**REMARKS/COMMENTS:**

The applicant requested for the inclusion of a 2.5 mg tablet of felodipine, extended release.

**CONCLUSIONS & RECOMMENDATIONS:**

The application is approvable from a manufacturing and controls standpoint. The expiry date of [redacted] in HDPE bottles with metal screw caps and CLIC-LOC closure and in Al-blisters packages is recommended.

cc: .  
Orig. NDA  
HFD-110/Division File  
HFD-110/Ram Mittal/date  
HFD-110/CSO

R/D Init by: RWolters/.

X /S/

Ramsharan D. Mittal Ph.D., Review Chemist  
filename: C:\NDA\19834\19834.008

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