

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-834/S012

Trade Name: Plendil

Generic Name: Felodipine

Sponsor: Astra Merck

Approval Date: August 7, 1997

Indications: The treatment of hypertension.

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

19-834/S012

CONTENTS

Reviews / Information Included in this NDA Review.

Approval Letter	X
Approvable Letter	
Labeling	
Summary Review	
Officer/Employee List	
Office Director Memo	
Cross Discipline Team Leader Review	
Medical Review(s)	
Chemistry Review(s)	X
Environmental Assessment	
Pharmacology Review(s)	
Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/Biopharmaceutics Review(s)	
Risk Assessment and Risk Mitigation Review(s)	
Proprietary Name Review(s)	
Administrative/Correspondence Document(s)	

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-834/S012

APPROVAL LETTER

NDA 19-834/S-012

AUG 7 1997

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

Dear Dr. Cushing:

Please refer to your supplemental new drug application (NDA) dated June 16, 1997 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Plendil (felodipine), 2.5mg, 5mg and 10mg Extended-Release Tablets.

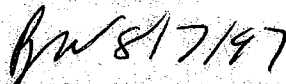
The user fee goal date is December 17, 1997.

The supplemental application provides for alternate secondary packaging of physicians samples by _____

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
Office of Drug Evaluation 1
Center for Drug Evaluation and Research

TRX 8-20A

cc: NDA 19-834/S-012
HFD-110/ DIV FILE
HFD-110/RMittal 8/04/97
HFD-110/ Project Manager
HFD-92
DISTRICT OFFICE
HFD-810/ Choiberg, DNDC Director
cg/8/04/97
Approval Date:

APPROVAL

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

19-834/S012

CHEMISTRY REVIEW(S)

AUG 5 1997

NDA 19-834

PLENDIL

ASTRA-MERCK

CHEMIST'S REVIEW		1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		4. Supplement(s) Number/Date 06-16-97	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates
7. Supplement provides for: Alternate secondary packaging for physician samples by _____			
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: See Review on next page.			
17. Conclusions and Recommendations: Satisfactory and approval letter is being sent.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature <i>R. Mittal</i>		Date Completed 08-04-97
19. Distribution: <input type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

TEEL T QUA

Walt
8/5/97

REVIEW NOTES:

The applicant submitted this supplement for the approval of alternate secondary packaging of physicians samples by _____ The applicant provided the following:

Package Component Description
Packaging Process Description

An EER for GMP inspection of the _____ was submitted on EES and acceptable status was recommended on July 31, 1997. A copy is attached. The supplement is satisfactory and approval letter is being sent.

CDER Establishment Evaluation Report
for August 04, 1997

Page 1 of 1

Application: NDA 19834/012
Stamp: 17-JUN-1997 Regulatory Due: 17-DEC-1997
Applicant: ASTRA MERCK
725 CHESTERBROOK BLVD
WAYNE, PA 190875677

Priority: 1S
Action Goal:
Brand Name: PLENDIL (FELODIPINE) TABS
Established Name:
Generic Name: FELODIPINE
Dosage Form: EXT (EXTENDED-RELEASE TABLET
Strength: 2.5 MG, 5 MG AND 10 MG

Org Code: 110

District Goal: 12-OCT-1997

FDA Contacts: D. ROEDER (HFD-111) 301-594-5300 , Project Manager
R. MITTAL (HFD-110) 301-594-5353 , Review Chemist
R. WOLTERS (HFD-110) 301-594-5376 , Team Leader

Overall Recommendation:

ACCEPTABLE on 31-JUL-1997 by M. EGAS (HFD-322) 301-594-0095

Establishment: _____

MF No:

AADA No:

Profile: TTR OAI Status: NONE
Last Milestone: OC RECOMMENDAT 31-JUL-1997
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Responsibilities:
FINISHED DOSAGE PACKAGER