

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-834/S005

Trade Name: Plendil

Generic Name: Felodipine

Sponsor: Astra Merck

Approval Date: February 5, 1996

Indications: The treatment of hypertension.

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APPLICATION NUMBER:

19-834/S005

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

19-834/S005

APPROVAL LETTER

2/21

NDA 19-834/S-005

FEB - 5 1996

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

Dear Dr. Cushing:

Please refer to your October 20, 1995 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PLENDIL (felodipine) Extended-Release, 2.5 mg, 5 mg, and 10 mg Tablets.

The supplemental application provides for packaging the 2.5 mg, 5 mg and 10 mg tablets in _____ in high density polyethylene bottles (HDPE) with non-child resistant plastic cap and induction seal foil lines.

We have completed the review of this supplemental application and the proposed container/closure system for 5 mg and 10 mg tablets is approved. For 2.5 mg tablets, please resubmit a separate supplement when data is available.

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,

RW 2/5/96

Robert Wolters, Ph.D.
Supervisory Chemist
Division of New Drug Chemistry, Cardio-Renal
Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:

Original NDA

HFD-110

HFD-110/Project Manager

HFD-80

HFD-232

HFD-110/RMittal/1/26/96

kc/1/29/96

Approval Date: July 25, 1991

APPROVAL

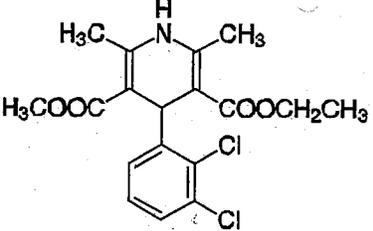
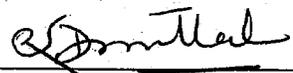
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APPLICATION NUMBER:

19-834/S005

CHEMISTRY REVIEW(S)

FEB - 5 1996

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 SCP-005 10-20-95	
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine		8. Amendments & Other (reports, etc) - Dates
7. Supplement provides for: Packaging the 2.5, 5, And 10 mg tablets in _____ HDPE bottles with non-child resistant plastic cap and induction seal liners.			
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 following pages.			
17. Conclusions and Recommendations: The proposed 24 ounce container/closure with new non-child resistant cap and induction sealed liner for the 5 mg and 10 mg tablets is approvable. For 2.5 mg tablets the applicant should provide at least 3 months accelerated and a commitment to continue the stability program similar to 5 mg and 10 mg tablets.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature 		Date Completed 01-25-96
19. Distribution: <input type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

Handwritten: JMD 1/25/96

2 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(4) Draft Labeling