CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: NDA 19834/S009

CHEMISTRY REVIEW(S)

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CHEMIST'S REVIEW	1. ORGANIZ HFD -		2. NDA Number 19-834		
3. Name and Address of Applicant (City & State) Astra Merck			4. Supplement(s) Number/Date		
725 Chesterbrook Bl Wayne, Pa 19087-567	SLR-013 (AF) 10-02-97				
5. Drug Name	6. Nonprop	rietary Name	8. Amendments & Other (reports,		
PLENDIL	Felodip	ine	etc) - Dates		
7. Supplement Provides	For:				
Final Printed Label	ing	, <u>.</u>			
9. Pharmacological Category 10. How Dispensed			11. Related IND(s)/ NDA(s)/DMF(s)		
Hypertension	<u> </u>	<u>/x</u> / RX // OTC	-		
12. Dosage Form(s)		13. Potency(ies) 2.5 mg, 5 mg			
Tablets		and 10 mg			
14. Chemical Name and Structure			15. Records/Reports		
<pre>(±) Ethylmethyl 4- dihydro-2,6-dimeth</pre>	Current				
			<u>/x</u> / Yes /_ / No		
H₃C N CH₃			Reviewed		
			<u>/x</u> / Yes /_ / No		
H₃COOC COOCH₂CH₃					
		•			
<u> </u>					
16. Comments:					
The applicant provided Final Printed Labeling as per Agency's letter of May 13, 1997 and subsequent response submitted on June 20, 1997 and telephone conversation with Mr. David Roeder of Agency.					
The labeling revisions did not effect "DESCRIPTION" AND " HOW SUPPLIED" sections.					
17. Conclusions and Recommendations:					
The "DESCRIPTION" AND " HOW SUPPLIED" sections remain satisfactory.					
18. REVIEWER					
Name Ramsharan D. Mittal	Signature	181	Date Completed		
19. Distribution: /_/ Original Jacket	+ / / -				
/ Original Jacke	<u>/_/ R</u>	Reviewer /_/ Divis:	ion File /_/ CSO		

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NDA 19-834

PLENDIL

ASTRA-MERCK

	 -				
CHEMIST'S REVIEW	1. ORGANIZ HFD -		2. NDA Number 19-834		
3. Name and Address of	3. Name and Address of Applicant (City & State)				
Astra Merck 725 Chesterbrook Blvd. Wayne, Pa 19087-5677			Number/Date SLR-009 (BL) 06-20-97		
5. Drug Name	6. Nonprop	rietary Name	8. Amendments &		
PLENDIL	Felodip	ine	Other (reports, etc) - Dates		
7. Supplement Provides	For:				
Revised labeling as 1997.	par Agency	's letter of May 13,			
9. Pharmacological Cat	9. Pharmacological Category 10. How Dispensed		11. Related IND(s)/		
Hypertension		<u>/x / RX / / OTC</u>	NDA(s)/DMF(s)		
12. Dosage Form(s) Tablets		13. Potency(ies) 2.5 mg, 5 mg and 10 mg			
	24	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 /x / Yes / / No		
H₃C、	H N, CH₃		Reviewed		
· Mac The Cha			/m / Waa / / w		
H ₉ COOC COOCH ₂ CH ₉			<u>/x</u> / Yes / / No		
	CI				
	~ Cl				
					
16. Comments:					
The circular for Plendil has been revised under CLINICAL PHARMACOLOGY, Pharmacokinetics and Metabolism subsection and DOSAGE AND ADMINISTRATION					
The labeling revisions did not effect "DESCRIPTION" AND " HOW SUPPLIED" sections.					
17. Conclusions and Recommendations:					
The "DESCRIPTION" AND " HOW SUPPLIED" sections remain satisfactory.					
18. REVIEWER					
Name Ramsharan D. Mittal	Signature	151-	Date Completed 07-07-97		
19. Distribution:/ Original Jacket/ Reviewer/ Division File / / CSO					
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CHEMIST'S REVIEW	1. ORGANIZ HFD -		2. NDA Number 19-834		
3. Name and Address of	Applicant	(City & State)	4. Supplement(s)		
Astra Merck			Number/Date		
725 Chesterbrook Bl	vd.		SLR-009		
Wayne, Pa 19087-567			09-19-96		
5. Drug Name	6. Nonprop	rietary Name	8. Amendments &		
PLENDIL	Felodip	ine	Other (reports, etc) - Dates		
7. Supplement Provides	For:				
Revised labeling.					
9. Pharmacological Cate	egory	10. How Dispensed	11 703-4-3 70-4		
Hypertension			11. Related IND(s)/ NDA(s)/DMF(s)		
12. Dosage Form(s)		/x / RX / / OTC			
Tablets		13. Potency(ies) 2.5 mg, 5 mg			
		and 10 mg	•		
	14. Chemical Name and Structure				
(±) Ethylmethyl 4-(dihydro-2.6-dimethy	<pre>(±) Ethylmethyl 4-(2,3-dichlorophenyl)-1,4- dihydro-2,6-dimethyl-3,5-pyridine-dicarboxylate.</pre>				
	armydio 2,0 dimethyl-3,5-pyridine-dicarboxylate.				
H ₃ C	· H₃C N CH₃				
H₃COOC	<u>/x</u> / Yes <u>/</u> / No				
·	CI				
•	OI.				
16. Comments:			AM 6.		
		Δ			
The circular for Plendil has been revised under CLINICAL PHARMACOLOGY, Pharmacokinetics and Metabolism and DOSAGE AND ADMINISTRATION to update the information on the effect of food on the property of the pr					
the information on the effect of food on the metabolism of felodipine.					
The labeling revisions did not effect "DESCRIPTION" AND " HOW SUPPLIED" sections.					
7. Conclusions and Recommendations:					
The "DESCRIPTION" AND " HOW SUPPLIED" sections remain satisfactory.					
18. REVIEWER					
Name	Signature	101			
Ramsharan D. Mittal	augrara	121	Date Completed 09-24-96		
9. Distribution: // Original Jacket / / Reviewer / / Division Piles					
			on File / / CSO		