CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

19-834/S016

Trade Name: Plendil

Generic Name: Felodipine

Sponsor: AstraZeneca LP

Approval Date: November 23, 1999

Indications: The treatment of hypertension.

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APPLICATION NUMBER:

19-834/S016

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Reviews / Information Included in this NDA Review.	
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Statistical Review(s)	
Microbiology Review(s)	
Clinical Pharmacology/ Biopharmaceutics Review(s)	
Administrative/Correspondence Document(s)	X

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APPLICATION NUMBER:

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APPROVAL LETTER

NOV 23 1999

NDA 19-834/S-016

AstraZeneca LP
Attention: Elliott T. Berger, Ph.D.
725 Chesterbrook Blvd
Wayne, PA 19087-5677

Dear Dr. Berger:

Please refer to your supplemental new drug application (NDA) dated July 23, 1999, received July 26, 1999, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Plendil (Felodipine) Extended-Release Tablets, 2.5 mg, 5.0 mg and 10 mg.

The supplemental application provides for alternate packaging of the drug product in a ——— ———Blister".

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,

K Srinivasachar 11-23-99

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I
Division of Cardio-Renal Drug Products (HFD-110)
Office of New Drug Chemistry
Center for Drug Evaluation and Research

cc:
Original NDA 19-834/S-016
HFD-110/Division File
HFD-110/DRoeder
HFD-110/RMittal
HFD-95
DISTRICT OFFICE
HFD-810/SimmonsJ
Init By: Srinivasachar
Drafted By: SO/11/23/99

Approval Date: 7/25/91

APPROVAL

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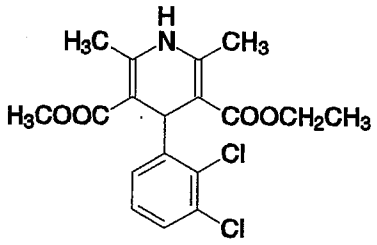
APPLICATION NUMBER:

19-834/S016

CHEMISTRY REVIEW(S)

NOV 23 1999

NDA 19-834 PLENDIL AstraZeneca

CHEMIST'S REVIEW	1. ORGANIZATION HFD - 110	2. NDA Number 19-834
3. Name and Address of Applicant (City & State) AstraZeneca 725 Chesterbrook Blvd. Wayne, Pa 19087-5677		4. Supplement(s) Number/Date SCM-016 7-23-99
5. Drug Name PLENDIL	6. Nonproprietary Name Felodipine	8. Amendments & Other (reports, etc) - Dates
7. Supplement Provides For: PRIOR APPROVAL SUPPLEMENT alternate packaging in a ———— Blister"		
9. Pharmacological Category Hypertension	10. How Dispensed /x/ RX /__/ 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 /x/ Yes /__/ No Reviewed /x/ Yes /__/ No
16. Comments: See review notes on following page.		
17. Conclusions and Recommendations: Satisfactory and recommended for approval.		
18. REVIEWER		
Name Ramsharan D. Mittal	Signature RDMittal	Date Completed 11-23-99
19. Distribution: /__/ Original Jacket /__/ Reviewer /__/ Division File /__/ CSO		

K. Srinivasachar
11-23-99

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

___ § 552(b)(5) Deliberative Process

___ § 552(b)(4) Draft Labeling

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APPLICATION NUMBER:

19-834/S016

ADMINISTRATIVE and CORRESPONDENCE DOCUMENTS

AstraZeneca

Fax

To	Dr. Ramsharan Mittal	**Fax number**	301-594-5494
Company	FDA		
From	Len Alansky	**Fax number**	610-695-4492
Date	23 November, 1999; 15:46	**Total pages**	1(1)
Subject	Reference NDA 19-834 Supplement S-016 dated July 23, 1999 Response to Questions on the Stability Data in Supplement S-016		

CONFIDENTIAL

Dear Dr. Mittal,

As requested during our telephone conversation this morning please find below the responses to your questions regarding the Plendil® ————blister stability data.

The stability data included in this supplement compared Plendil 2.5 and 10 mg tablets packaged in the current blister components to the alternate proposed blister components. This data is intended to bracket the Plendil 5 mg tablets which is also planned to be packaged in the alternate blister components.

The Plendil 10 mg comparative stability data in this supplement was generated from studies that began in early 1994. Internally the addition of an alternate supplier for Plendil blister components was not a high priority therefore a decision was made to wait and collect stability data for the newly approved Plendil 2.5 mg tablet in the alternate blister. Therefore, the Plendil 2.5 mg comparative stability data was generated from studies that began in mid 1997.

Please let me know if you have additional questions.

Sincerely,

Len Alansky
CMC Manager

cc: Emery Gigger (AZLP)

AstraZeneca L.P.
725 Chesterbrook Blvd
Wayne, PA 19087

Tel +1 610 695 1000

1 Page(s) Withheld

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