CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE FOR:

APPLICATION NUMBER
20-364/SE8-016

Chemistry Review(s)

CHEMIST'S REVIEW #1

1. ORGANIZATION	2. NDA NUMBER
HFD-150 DODP	20-364

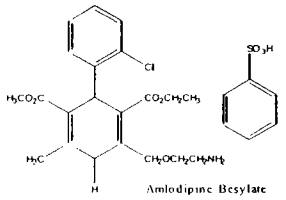
3. NAME AND ADDRESS OF APPLICANT (*City and State*)	4. AF NUMBER	
Novartis Pharmaceuticals Corporation 59 Route 10, East Hanover, NJ 07936-1080.		
	5. SUPPLEMENT (S) NUMBER(S)	DATES(S)

6. NAME OF DRUG	7. NONPROPRIETARY NAME		
Lotrel® (amlodipine and Benazepril HCl)	Amlodipine and benazepril HCl	SE8-016	06-29-2001

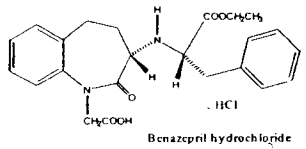
8. SUPPLEMENT PROVIDES FOR: A new higher dosage strength that combines 10 mg of amlodipine plus 20 mg of benazepril HCl in a capsule for oral administration.	9. AMENDMENTS DATES BC 12.14.2001 BC 02.20.2002

10. PHARMACOLOGICAL CATEGORY	11. HOW DISPENSED	12. RELATED IND/NDA/DMF
Hypertension	RX ✔ OTC	
13. DOSAGE FORM(S) Capsule	14. POTENCY 2.5/10, 5/10, 5/20 and 10/20 mg	

15. CHEMICAL NAME AND STRUCTURE



Amlodipine Besylate



Benazepril hydrochloride

16. RECORDS AND REPORTS

CURRENT YES__ NO
REVIEWED YES__ NO

17. COMMENTS

This prior approval supplement provides for A new higher dosage strength that combines 10 mg of amlodipine plus 20 mg of benazepril HCl in a capsule for oral administration.

18. CONCLUSIONS AND RECOMMENDATIONS

The office of compliance has given an overall acceptable recommendation for manufacturing sites. This application is recommended for approval from the standpoint of chemistry, manufacturing and controls. Before this application is approved, the applicant should provide final printed labeling and final printed labels (container/carton labels) incorporating agreed upon changes.

19. REVIEWER

NAME	SIGNATURE	DATE COMPLETED
Nallaperumal Chidambaram, Ph.D.	S	02-27-2002

DISTRIBUTION	ORIGINAL NDA	DIVISION FILE	Reviewer: N. Chidambaram Ph.D., HFD-150	CSO: J. Guzman HFD-110	Chemistry Team Leader: K. Srinivasachar, Ph.D.
DNDC1/Division Dir. /DY. Director					

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FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: **NDA 20364/016**
Priority: **4S**
Org Code: **110**
Stamp: **02-JUL-2001** Regulatory Due: **02-MAY-2002**
Action Goal:
District Goal: **28-MAR-2002**
Applicant: **NOVARTIS PHARMS**
59 RT 10
EAST HANOVER, NJ 079361080
Brand Name: **LOTREL**
Established Name:
Generic Name: **AMLODIPINE BESYLATE; BENAZEPRIL HYDROCHL**
Dosage Form: **CAP (CAPSULE)**
Strength: **10/2.5,10/5, & 20/5 MG**

FDA Contacts: **ID = 127376** **, Project Manager**
N. CHIDAMBARAM (HFD-810) **301-594-5752 , Review Chemist**
K. SRINIVASACHAR (HFD-110) **301-594-5376 , Team Leader**

Overall Recommendation:

ACCEPTABLE on 27-AUG-2001 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: [redacted]
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **21-AUG-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities: [redacted]

Establishment: **2416082**
NOVARTIS PHARMA INC (CIBA)
OLD MILL RD
SUFFERN, NY 10901
DMF No:
AADA No:

Profile: **CHG** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **27-AUG-2001**
Decision: **ACCEPTABLE**
Reason: **DISTRICT RECOMMENDATION**
Responsibilities: **FINISHED DOSAGE MANUFACTURER**

Establishment: **2210396**
NOVARTIS PHARMA INC (SANDOZ)
59 RT 10
EAST HANOVER, NJ 079361080
DMF No:
AADA No:

Profile: **CTL** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **21-AUG-2001**
Responsibilities: **FINISHED DOSAGE OTHER TESTER**

ESTABLISHMENT EVALUATION REQUEST SUMMARY REPORT

Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Establishment: [redacted]

DMF No:
AADA No:

Profile: **CHG** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **21-AUG-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: [redacted]

Establishment: [redacted]

DMF No:
AADA No:

Profile: **CHG** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **21-AUG-2001**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities: [redacted]

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/s/

Nallaperumal Chidambaram
2/27/02 04:03:07 PM
CHEMIST

Kasturi Srinivasachar
2/27/02 06:27:46 PM
CHEMIST