020757__S007

NDA 20-757/S-007

MAR 16 1999

Bristol-Myers Squibb
Attention: Melody A. Brown
P.O. Box 5400
Princeton, NJ 08543

Dear Ms. Brown:

Please refer to your supplemental new drug application dated September 23, 1998, received September 24, 1998, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro (irbesartan) Tablets, 75 mg, 150 mg and 300 mg.

The supplemental application provides for [redacted] as an alternate manufacturer of irbesartan [redacted] in the synthesis of the drug substance, irbesartan.

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 3-16-99
Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: Sanofi Pharmaceuticals, Inc.
Attention: Gregory Torre, Ph.D., J.D.
90 Park Avenue
New York, NY 10016

cc: NDA 20-757/S-007
HFD-110/ DIV FILE
HFD-110/RMittal 03/08/99
HFD-110/ Project Manager/KBongiovanni
HFD-92
DISTRICT OFFICE
HFD-810/CHoiberg
cg 03/08/99

Approval Date: September 30, 1997

APPROVAL

MAR 16 1999

DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

CHEMIST'S REVIEW	1. ORGANIZATION HFD - 110	2. NDA Number 20-757
3. Name and Address of Applicant (City & State) Bristol Myers Squibb Company P. O. Box 4000 Princeton, NJ 08543-4000		4. Supplement(s) Number(s) Date(s) SCM-007 23/09/98
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates

7. **Supplement Provides for:** SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

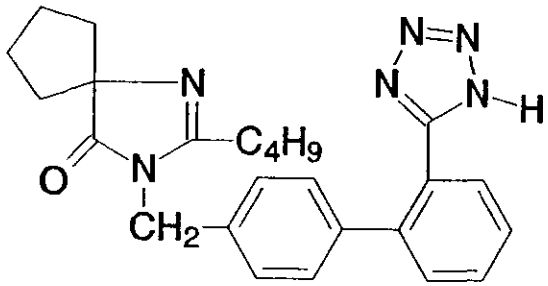
The approval of [ ] facility, [ ] as an alternative manufacturer of irbesartan [ ] in the synthesis of the irbesartan drug substance.

The changes being effected date is October 15, 1998.

9. Pharmacological Category	10. How Dispensed	11. Related IND(s)/ NDA(s)/DMF(s)
Angiotensin II Receptor Antagonist/Hypertension	/x/ RX /__/ OTC	NDA 20-758 DMF's [ ] and [ ]
12. Dosage Form(s) Tablets	13. Potency(ies) 75 mg, 150mg, and 300 mg.	

14. **Chemical Name and Structure**

2-Butyl-3-[(2'-(1H-tetrazol-5-yl)biphenyl-4-yl) methyl]-1,3-diazaspiro[4.4]non-1-en-4-one.



15. **Records/Reports**

Current

/x/ Yes /__/ No

Reviewed

/x/ Yes /__/ No

16. **Comments:** A request for inspection was submitted on September 25, 1998. As of September 28, 1998, the status of EER is acceptable and a copy of the EER report is attached at the end of this review.

17. **Conclusions and Recommendations:**
Satisfactory and recommended for approval.

18. **REVIEWER**

Name	Signature	Date Completed
Ramsharan D. Mittal	RDMittal	03/2/99

19. Distribution:
/__/ Original Jacket /__/ Reviewer /__/ Division File /__/ CSO

K. Srinivasan
3-2-99

2 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

CDER Establishment Evaluation Report for December 14, 1998

Application: **NDA 20757/007**
Stamp: **24-SEP-1998** Regulatory Due: **24-MAR-1999**
Applicant: **SANOFI PHARMS**
90 PARKE AVE
NEW YORK, NY 10016

Priority: **1S** Org Code: **110**
Action Goal: District Goal: **20-DEC-1998**
Brand Name: **AVAPRO (IRBESARTAN) TABS 75/150/300 MG**
Established Name:
Generic Name: **IRBESARTAN TABS 75/150/300MG**
Dosage Form: **TAB (TABLET)**
Strength: **75, 150, 300MG**

FDA Contacts:
K. BONGIOVANNI (HFD-110) **301-594-5300 , Project Manager**
R. MITTAL (HFD-110) **301-594-5353 , Review Chemist**
K. SRINIVASACHAR (HFD-110) **301-594-5376 , Team Leader**

Overall Recommendation:

ACCEPTABLE on 29-SEP-1998 by S. FERGUSON (HFD-324) 301-827-0062

Establishment:

DMF No: [redacted]
AADA No:

Profile: CSN OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **29-SEP-1998**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**

Responsibilities:

Appears This Way
On Original