020757__S009

NOV 2 - 1999

NDA 20-757/S-009

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

Dear Dr. Torre:

Please refer to your supplemental new drug application (NDA) dated July 9, 1999, received July 13, 1999, 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 the use of an alternative [redacted] that [redacted].

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 11-2-99
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:
Bristol-Myers Squibb Company
Attention: Melody Brown
P.O. Box 5400
Princeton, NJ 08543-5400

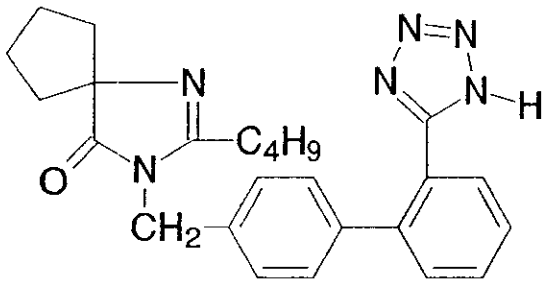
CC:
Original NDA 20-757/S-009
HFD-110/Division File
HFD-110/DRoeder
HFD-110/RMittal
HFD-95
DISTRICT OFFICE
HFD-810/Jsimmons
Init. by: Ksrinivasachar
Drafted by: SO/11/2/99

Approval Date: 9/30/97

APPROVAL

NOV 1 - 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-009 07/09/99
5. **Drug Name** Avapro	6. **Nonproprietary Name** Irbesartan	7. **Amendments & Other (reports, etc) - Dates**
7. **Supplement Provides for:** SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED an alternative [ ] The changes being effected date is August 9, 1999.		
9. **Pharmacological Category** Angiotensin II Receptor Antagonist/Hypertension	10. **How Dispensed** /x/ RX /__/ OTC	11. **Related IND(s)/ NDA(s)/DMF(s)** 20-758,
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:** See Review Notes.		
17. **Conclusions and Recommendations:** Satisfactory and recommended for approval.		
18. **REVIEWER**		
Name Ramsharan D. Mittal	**Signature** RDMittal	**Date Completed** 10/27/99
19. Distribution: /__/ Original Jacket /__/ Reviewer /__/ Division File /__/ CSO		

K. Dunivedi
11-1-99

3 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 20757/009
Stamp: 13-JUL-1999
Regulatory Due: 13-NOV-1999
Applicant: SANOFI PHARMS
90 PARKE AVE
NEW YORK, NY 10016
Priority: 1S
Org Code: 110

Action Goal:
District Goal: 09-OCT-1999
Brand Name: AVAPRO (IRBESARTAN) TABS 75/150/300 MG
Estab. Name:
Generic Name: IRBESARTAN TABS 75/150/300MG

Dosage Form: (TABLET)
Strength: 75, 150, 300MG

Application Comment: THIS LEVEL 2 CBE SUPPLEMENT PERTAINS TO AN ALTERNATIVE [ ] CHANGE WILL BE EFFECTIVE AUG 8, 1999. (on 19-JUL-1999 by F. ZIELINSKI (HFD-110) 301-594-5300)

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

Overall Recommendation: ACCEPTABLE on 19-JUL-1999 by S. FERGUSON (HFD-324) 301-827-0062

Establishment: 1819504
BRISTOL MYERS SQUIBB CO
2400 WEST LLOYD EXPY
EVANSVILLE, IN 477210001

DMF No: AADA:
Responsibilities: INTERMEDIATE MANUFACTURER
Profile: TCM OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	19-JUL-1999				ZIELINSKIF
OC RECOMMENDATION	19-JUL-1999			ACCEPTABLE BASED ON PROFILE	FERGUSONS