020757___S012

APR 28 2000

NDA 20-757/S-012

Bristol-Myers Squibb Company
Attention: Melody Brown
P.O. Box 5400
Princeton, New Jersey 08543-5400

Dear Ms. Brown:

Please refer to your supplemental new drug application (NDA) dated November 8, 1999, received November 9, 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 an amendment to the [ ] test method for [ ] 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 4-28-00
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:
Sanofi Pharmaceuticals, Inc.
Attention: Gregory Torre, Ph.D., J.D.
90 Park Avenue
New York, NY 10016

cc:
Original NDA 20-757/S-012
HFD-110/DIVISION FILE
HFD-110/RMittal
HFD-110/Project Manager/D.Roeder
HFD-95
DISTRICT OFFICE
HFD-810/JSimmons
Init: by KSrinivasachar
Draft by: TArcher 4/25/00

Approval Date: 9/30/97

APPROVAL

APR 28 2000

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 5400 Princeton, NJ 08543-5400		4. Supplement(s) Number(s) Date(s) SCM-012 11/08/99
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates
7. Supplement Provides for: CHANGES BEING EFFECTED the amendment of the [ ] test for [ ] irbesartan.		
9. Pharmacological Category Angiotensin II Receptor Antagonist/Hypertension	10. How Dispensed /x/ RX / / OTC	11. Related IND(s)/ NDA(s)/DMF(s) NDA 20-758 DMF [redacted] DMF [redacted]
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: CBE Supplement.		
17. Conclusions and Recommendations: Recommended for approval.		
18. REVIEWER		
Name Ramsharan D. Mittal	Signature R D Mittal	Date Completed 04/21/00
19. Distribution: / / Original Jacket / / Reviewer / / Division File / / CSO		

K. Srinivasacha
4-25-00

1 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling