

020757 — 5012

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 \square test method for \square 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

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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

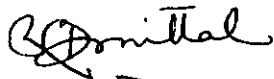
Draft by: TArcher 4/25/00

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 <input type="checkbox"/> test for <input checked="" type="checkbox"/> irbesartan.			
9. Pharmacological Category Angiotensin II Receptor Antagonist/Hypertension		10. How Dispensed <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	11. Related IND(s)/ NDA(s)/DMF(s) NDA 20-758 DMF <input type="checkbox"/> DMF <input type="checkbox"/>
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 <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Reviewed <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
16. Comments: CBE Supplement.			
17. Conclusions and Recommendations: Recommended for approval.			
18. REVIEWER			
Name Ramsharan D. Mittal	Signature 		Date Completed 04/21/00
19. Distribution: <input type="checkbox"/> / Original Jacket <input type="checkbox"/> / Reviewer <input type="checkbox"/> / Division File <input type="checkbox"/> / CSO			

K. Animivasa
4-25-00

1 Page(s) Withheld

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

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling