020757—S008

NDA 20-757/ S-008

MAR 16 1999

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

Dear Ms. Brown:

Please refer to your October 30, 1998 supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro (irbesartan) 75 mg, 150 mg and 300 mg, Tablets.

The supplemental application provides for an additional manufacturing site for the drug substance, irbesartan, at Swords Laboratories, Dublin, Ireland.

We have completed the review of this supplemental application and it is approved with the understanding that you will submit ' stability data on drug product manufactured using irbesartan synthesized at Swords Laboratories, as soon as they are available.

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-008
HFD-110/ DIV FILE
HFD-110/Rmittal 03/12/99
HFD-110/Project Manager/KBongiovanni
HFD-92
DISTRICT OFFICE
HFD-810/ CHoiberg
cg 03/12/99

Approval Date: September 30, 1997

APPROVAL

DF

MAY 5 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 4000 Princeton, NJ 08543-4000		4. Supplement(s) Number(s) Date(s) SNC-008 02/14/00
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates

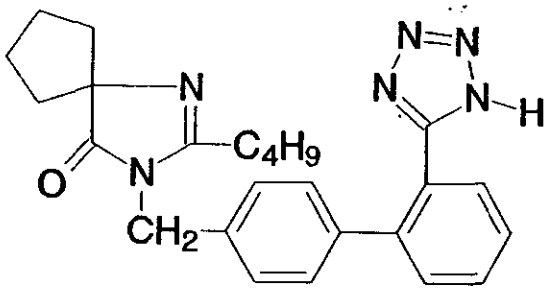
7. **Supplementary New Correspondence Provides for:**

[ ], stability data (one lot each strength) on the drug product manufactured from the Swords Co. produced drug substance.

9. Pharmacological Category	10. How Dispensed	11. Related IND(s)/ NDA(s)/DMF(s)
Angiotensin II Receptor Antagonist/Hypertension	/x/ RX /__/ OTC	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 no reply is required.

18. **REVIEWER**

Name	Signature	Date Completed
Ramsharan D. Mittal	RDMittal	4/17/00

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

K. Srinivasachar
5-5-00

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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-008 10/30/98
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates

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

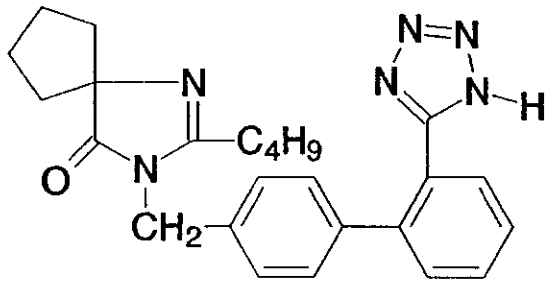
The approval of Swords Laboratories facility, Swords Co. Dublin, Ireland, as an alternative manufacturer of irbesartan drug substance.

The changes being effected date is November 30, 1998.

9. Pharmacological Category	10. How Dispensed	11. Related IND(s)/ NDA(s)/DMF(s)
Angiotensin II Receptor Antagonist/Hypertension	/x/ RX /___/ OTC	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	Signature	Date Completed
Ramsharan D. Mittal	RDMittal	2/22/99

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

K. Srinivasa
3-2-99

Application: **NDA 20757/008**
Priority: **1S** Org Code: **110**
Stamp: **02-NOV-1998** Regulatory Due: **02-MAR-1999**
Action Goal: District Goal: **26-JAN-1999**
Applicant: **SANOFI PHARMS**
90 PARKE AVE
NEW YORK, NY 10016
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 04-NOV-1998 by J. D AMBROGIO (HFD-324) 301-827-0062

Establishment: **9610172**
BRISTOL MYERS SQUIBB
WATERY LANE
DUBLIN, SWORDS COUNTY, EI
DMF No:
AADA No:

Profile: **CSN** OAI Status: **NONE**
Last Milestone: **OC RECOMMENDATION**
Milestone Date **04-NOV-1998**
Decision: **ACCEPTABLE**
Reason: **BASED ON PROFILE**
Responsibilities: **DRUG SUBSTANCE MANUFACTURER**

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On Original

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