020757__5002

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JAN 30 1998

NDA 20-757/ S-002

Bristol-Myers Squibb
Attention: Douglas B. Hay, Ph.D.
P.O. Box 4000
Princeton, NJ 08543-4000

Dear Dr. Hay:

Please refer to your December 15, 1997 supplemental new drug application (NDA) 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 user fee goal date is June 17, 1998.

The supplemental application provides for a new [ ] method for the [ ] used in the synthesis of 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,

/S/

James H. Short, Ph.D.
Acting Chemistry Team Leader, DNDC I
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

cc: NDA 20-757/ S-002
HFD-110/ DIV FILE
HFD-110/ RMittal
HFD-110/ Project Manager/ KBongiovanni
HFD-92
DISTRICT OFFICE
HFD-810/ CHoiberg
cg/01/27/98

Approval Date: September 30, 1997

APPROVAL

JAN 30 1998

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

NDA #: 20-757/SCS-002 **REVIEW DATE:** 20-JAN-98

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SCS-002	15-DEC-97	17-DEC-97	18-DEC-97

NAME & ADDRESS OF APPLICANT

Bristol Myers Squibb Company
P. O. Box 4000
Princeton, NJ 08543-4000

SUPPLEMENT PROVIDES FOR:

SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

A new [ ] method for [ ] in the synthesis of drug substance irbesartan.

DRUG PRODUCT NAME

Established Name:	Irbesartan
Proprietary:	AVAPRO
Nonproprietary/USAN:	Irbesartan
Code Name/#:	SR 47,436, BMS-186295, BMS-186295-01
Chem.Type/Ther.Class:	1/S

AND Suitability Petition/DESI/Patent Status:

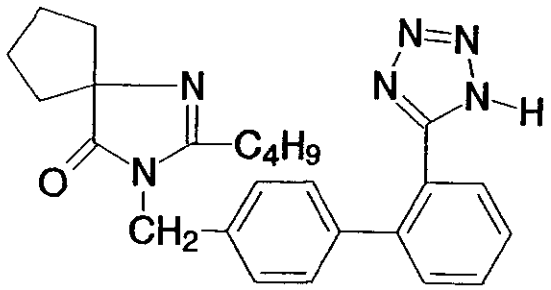
The U.S. Patent 5,270,317 held by Elf Sanofi was issued for irbesartan and is due to expire on March 2011.

PHARMACOL.CATEGORY/INDICATION: Angiotensin II Receptor Antagonist/Hypertension
DOSAGE FORM: TABLETS
STRENGTH 75 mg, 150 mg and 300 mg.
ROUTE OF ADMINISTRATION: ORAL
DISPENSED: Rx

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

CAS # 138402-11-6 **MOLECULAR FORMULA** $C_{25}H_{28}N_6O$ **MOLECULAR WEIGHT** 428.5

STRUCTURAL FORMULA



SUPPORTING DOCUMENTS:

None

RELATED DOCUMENTS (if applicable): NDA 20-758 Irbesartan/Hydrochlorothiazide

CONSULTS: None at present.

REMARKS/COMMENTS:

None

CONCLUSIONS & RECOMMENDATIONS:

Satisfactory and approval letter is being sent.

cc:
HFD-110/Division File
HFD-110/Ram Mittal/date
HFD-110/CSO

R/D Init by: JShort/
James H Short
1-22-98

R D Mittal

Ramsharan D. Mittal Ph.D., Review Chemist
fileame: C:\NDA\20757\20757S.002

1 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling