

020757_5001

NOV 10 1997

NDA 20-757/S-001

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

Dear Dr. Hays:

Please refer to your October 24, 1997 supplemental new drug application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro (irbesartan) Tablets 75, 150 and 300 mg.

We acknowledge receipt of your communication dated November 10, 1997.

The supplemental application provides for changes in the τ π process for the manufacture of the drug substance irbesartan and introduction of τ π π in the irbesartan drug substance control monograph. 3

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/

Robert J. Wolters, Ph.D.
Chemistry Team Leader, DNDC I
Division of Cardio-Renal Drug Products
Office of Pharmaceutical Sciences
Center for Drug Evaluation and Research

cc:

Original NDA

~~HFD-110~~

HFD-110/Kathleen Bongiovanni

HFD-110/Mittal

HFD-80

DISTRICT OFFICE

HFD-810/C. Hoiberg

w/11/10/97

JAN 22 1998

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

NDA #: ~~287-757~~ SNC-S001 REVIEW DATE: 20-JAN-98

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SNC-S001	12-NOV-97	13-NOV-97	14-NOV-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

The revised irbesartan drug substance [modifications made in the drug substance manufacture at the Sanofi Aramon facility.

DRUG PRODUCT NAME

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

AND Suitability Petition/DESI/Patent Status:

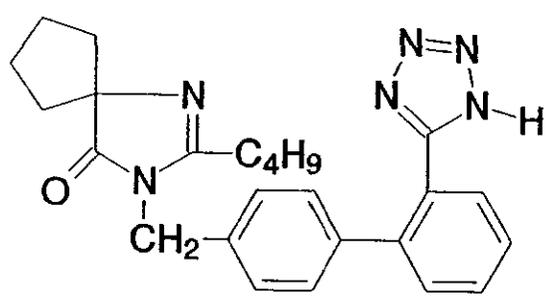
The U.S. Patent 5,270,317 held by Elf Sanofi was issued for irbesartan and is due to expire on March 2011.

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 C₂₅H₂₈N₆O 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, approval letter was sent earlier and no reply is necessary.

cc:

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

R/D Init by: JShort/
J Short
1/22/98



Ramsharan D. Mittal Ph.D., Review Chemist
fileame: C:\NDA\20757\20757SNC.001

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

 § 552(b)(5) Deliberative Process

 § 552(b)(5) Draft Labeling

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NOV 10 1997

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

NDA #: 20-757/S-001 REVIEW DATE: 10-NOV-97

SUBMISSION TYPE	DOCUMENT DATE	CDER DATE	ASSIGNED DATE
SCS -001	24-OCT-97	27-OCT-97	28-OCT-97

NAME & ADDRESS OF SPONSOR

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

SUPPLEMENT PROVIDES FOR:

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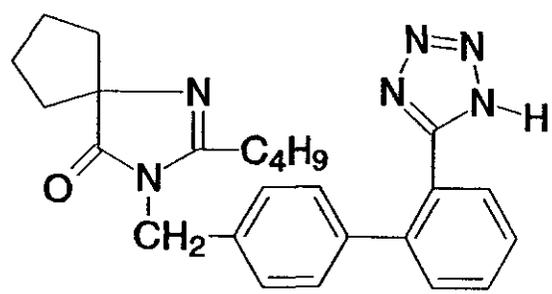
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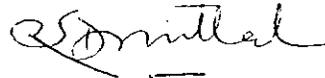
None

CONCLUSIONS & RECOMMENDATIONS:

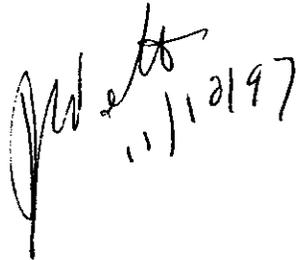
Satisfactory and approval letter is being sent.

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

R/D Init by: RWolters/



Ramsharan D. Mittal Ph.D., Review Chemist
filename: C:\NDA\20757\20757S.001



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