

020 757—5023



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757/S-023

Sanofi-Synthelabo
C/o Bristol-Myers Squibb Company
Attention: David Ziering, Ph.D.
P. O. Box 5400
Princeton, NJ 08543-5400

Dear Dr. Ziering:

Please refer to your supplemental new drug application dated September 27, 2002, received September 30, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro (irbesartan) Tablets, 75 mg, 150 mg and 300 mg.

This "Changes Being Effected in 30 Days" supplemental new drug application provides for utilization of _____ as an alternative to the approved _____ blister flex material for Avapro Tablets.

We have completed our review of this supplemental application. This supplement is approved.

We remind you that you must comply with the reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any question, please call Edward Fromm, Regulatory Health Project Manager, at (301) 594-5332.

Sincerely,

/s/

Kasturi Srinivasachar, Ph.D.
Chemistry Team Leader, DNDC I for the
Division of Cardio-Renal Drug Products (HFD-110)
DNDC I, Office of New Drug Chemistry
Center for Drug Evaluation and Research

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/s/

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

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-023 09/27/02
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates
7. Supplement Provides for: CHANGES BEING EFFECTED in 30 days the approval to utilize — as an alternative to the approved — blister flex material for Avapro Tablets.		
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
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: A CBE-30 Supplement as per Changes to An Approved NDA or ANDA.		
17. Conclusions and Recommendations: Based on the submitted stability data the current expiry date of 24 months is supported for Avapro tablets in — blisters and supplement may be approved.		
18. REVIEWER Ramsharan D. Mittal		

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/s/

Ramsharan Mittal
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CHEMIST

Kasturi Srinivasachar
3/21/03 04:02:20 PM
CHEMIST



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757/S-023

Sanofi-Synthelabo c/o Bristol-Myers Squibb
Attention: David Ziering, Ph.D.
P.O. Box 4000
Princeton, New Jersey 08543-4000

Dear Dr. Ziering:

We have received your supplemental drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

Name of Drug Product: Avapro (irbesartan) 75, 150, and 300 mg Tablets

NDA Number: 20-757

Supplement number: S-023

Date of supplement: September 27, 2002

Date of receipt: September 30, 2002

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, this application will be filed under section 505(b) of the Act on November 29, 2002 in accordance with 21 CFR 314.101(a).

All communications concerning this supplement should be addressed as follows:

U.S. Postal Service:

Center for Drug Evaluation and Research
Division of Cardio-Renal, HFD-110
Attention: Division Document Room
5600 Fishers Lane
Rockville, Maryland 20857

Courier/Overnight Mail:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Cardio-Renal, HFD-110
Attention: Document Room
1451 Rockville Pike
Rockville, Maryland 20852

If you have any question, please call:

Mr. Edward Fromm
Regulatory Health Project Coordinator
(301) 594-5332

Sincerely yours,

Zelda McDonald
Acting Chief, Project Management Staff
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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/s/

Zelda McDonald
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