

020757—5018



NDA 20-757/S-018

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

Dear Ms. Brown:

Please refer to your supplemental new drug application dated October 13, 2000, received October 16, 2000, 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" supplemental new drug application provides for the removal of packaging system for the drug product.

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.

If you have any questions, call Edward Fromm, Regulatory Project Manager, at (301) 594-5313.

Sincerely,

{See appended electronic signature page}

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

cc:

Sanofi Pharmaceuticals, Inc.
Attention: Gregory Torre, Ph.D., J.D.
90 Park Avenue
New York, NY 10016

/s/

Kasturi Srinivasachar
2/2/01 11:10:40 AM

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-018 10/13/00
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates
7. Supplement Provides for: CHANGES BEING EFFECTED SUPPLEMENT an approval to implement the removal of .L packaging system. J		
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
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 Effective October 30, 2000.		
17. Conclusions and Recommendations: Satisfactory and recommended for approval.		
18. REVIEWER		
Name Ramsharan D. Mittal	Signature	Date Completed 02/01/01
19. Distribution: <input type="checkbox"/> Original Jacket <input type="checkbox"/> Reviewer <input type="checkbox"/> Division File <input type="checkbox"/> CSO		

1 Page(s) Withheld

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

§ 552(b)(5) Deliberative Process

§ 552(b)(5) Draft Labeling

/s/

Ramsharan Mittal
2/1/01 04:28:55 PM
CHEMIST

Kasturi Srinivasachar
2/1/01 06:27:11 PM
CHEMIST



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville MD 20857

NDA 20-757/S-018

Sanofi-Synthelabo, Inc.
c/o Bristol-Myers Squibb Pharmaceutical Research Institute
Attention: Ms. Melody A. Brown
P.O. Box 5400
Princeton, NJ 08543-5400

Dear Ms. Brown:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: Avapro (irbesartan) Tablets

NDA Number: 20-757

Supplement Number: S-018

Date of Supplement: October 13, 2000

Date of Receipt: October 16, 2000

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on December 15, 2000 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Center for Drug Evaluation and Research
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation I
Attention: Document Control Room 5002
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/s/

Natalia A. Morgenstern
Chief, Project Management Staff
Division of Cardio-Renal Drug Products, HFD-110
Office of Drug Evaluation I
Center for Drug Evaluation and Research

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cc:

Original NDA 20-757/S-018
HFD-110/Div. Files
HFD-110/CSO/Edward Fromm

Filename: G:\PM Folder\NDA ltrs\20757s18.doc

SUPPLEMENT ACKNOWLEDGEMENT

/s/

Natalia Morgenstern
12/14/00 05:58:23 PM