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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-757/S-020

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 December 11, 2000, received December 13, 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 in 30 days" supplemental new drug application provides for the [ ] located at the approved Sanofi-Chimie, Aramon, France site as an alternate facility for the manufacture of the 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.

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

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/s/

Kasturi Srinivasachar
6/7/01 05:46:40 PM

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) SCS-020 12/11/01
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates
7. Supplement Provides for: CHANGES BEING EFFECTED IN 30 DAYS registration of the [ ] located at the approved Sanofi-Chimie, Aramon, France site for the manufacture of irbesartan drug substance.		
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: CBE in 30 Days Supplement, Effective Date January 14,2001. EER is acceptable and a copy is attached at the end of this review. DMF # [ ] has been reviewed and is satisfactory.		
17. Conclusions and Recommendations: The changes reported in the manufacturing of drug substance involve [ ] at already approved site. EER status is acceptable. Such supplements can be accepted as a CBE in 30 days and the supplement is recommended for approval.		
18. REVIEWER		
Name Ramsharan D. Mittal	Signature	Date Completed 04/30/01
19. Distribution: /__/ Original Jacket /__/ Reviewer /__/ Division File /__/ CSO		

1 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

11-APR-2001 FDA CDER EES Page 1 of 1
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 20757/020
Stamp: 13-DEC-2000
Regulatory Due: 13-JUN-2001
Applicant: SANOFI SYNTHELABO
90 PARK AVE
NEW YORK, NY 100161389
Priority: 1S
Org Code: 110

Action Goal:
District Goal: 09-MAY-2001
Brand Name: AVAPRO (IRBESARTAN) TABS 75/150/300 MG
Estab. Name:
Generic Name: IRBESARTAN TABS 75/150/300MG

Dosage Form: (TABLET)
Strength: 75, 150, 300MG

Application Comment: NEW FACILITY FOR THE DRUG SUBSTANCE INTERMEDIATE (on 04-JAN-2001 by R. MITTAL (HFD-110) 301-594-5353)
TO REGISTER [ ] AT THE APPROVED SANOFI CHIMIE, ARAMON, FRANCE SITE. (on 10-JAN-2001 by R. MITTAL (HFD-110) 301-594-5353)

FDA Contacts: E. FROMM (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 11-JAN-2001 by M. GARCIA (HFD-322) 301-594-0095

Establishment: 9611687
SANOFI CHIMIE
30390
ARAMON, , FR

DMF No:
AADA:
Responsibilities: DRUG SUBSTANCE MANUFACTURER
Profile: CSN
OAI Status: NONE
Estab. Comment:

Milestone Name	Date	Req. Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	11-JAN-2001				MITTALR
OC RECOMMENDATION	11-JAN-2001			ACCEPTABLE BASED ON PROFILE	EGASM

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/s/

Ramsharan Mittal
6/6/01 12:31:04 PM
CHEMIST

Kasturi Srinivasachar
6/6/01 01:21:42 PM
CHEMIST