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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757 / S-022

Sanofi-Synthelabo, Inc.
Attention: David Ziering, Ph.D.
90 Park Avenue
New York, NY 10016

Dear Dr. Ziering:

Please refer to your supplemental new drug application dated January 24, 2002, received January 25, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro, (irbesartan) Tablets 75 mg, 150mg and 300mg.

We acknowledge receipt of your submission dated July 18, 2002.

This "Changes Being Effected in 30 days" supplemental new drug application provides for Sanofi Winthrop Industrie, Ambares, France as an alternative drug product manufacturing and release testing site.

We have completed our review of this application, as amended and it is approved. Please provide final printed labeling (FPL) in your next annual report.

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

If you have any questions, call Edward Fromm, Regulatory Project Manager, at (301) 594-5300.

Sincerely,

{See appended electronic signature page} /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
7/19/02 05:34:50 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) SCM-022 01/24/02
5. Drug Name Avapro	6. Nonproprietary Name Irbesartan	7. Amendments & Other (reports, etc) - Dates SCM-022(BC) 7/18/02
7. Supplement Provides for: CHANGES BEING EFFECTED IN 30 DAYS addition of an alternate drug product manufacturing site.		
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, 150 mg, and 300 mg.	
14. Chemical Name 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 February 18, 2002.		
17. Conclusions and Recommendations: The changes reported in the manufacturing of drug product involve addition of alternate drug product manufacturing site. EER status is acceptable. COAs, dissolution profiles, and stability data is satisfactory. Such supplements can be accepted as a CBE-30 and the supplement is approved.		
18. REVIEWER		
Name Ramsharan D. Mittal		Date Completed 07/18/02

7 Page(s) Withheld

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

19-JUL-2002

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Application: NDA 20757/022
Stamp: 25-JAN-2002 Regulatory Due: 25-JUL-2002
Applicant: SANOFI SYNTHELABO
90 PARK AVE
NEW YORK, NY 10016

Priority: 1S Org Code: 110
Action Goal: District Goal: 20-JUN-2002
Brand Name: AVAPRO (IRBESARTAN) TABS 75/150/300 MG
Established Name:
Generic Name: IRBESARTAN TABS 75/150/300MG
Dosage Form: TAB (TABLET)
Strength: 75, 150, 300MG

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 16-MAY-2002 by S. FERGUSON (HFD-324) 301-827-0062

Establishment: 9611342
SANOFI WINTHROP INDUSTRIE
33440
AMBARES, , FR

DMF No:
AADA No:

Profile: TCM OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 16-MAY-2002
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

Responsibilities: FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE RELEASE TESTER

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/s/

Ramsharan Mittal
7/19/02 05:05:38 PM
CHEMIST

Kasturi Srinivasachar
7/19/02 05:17:48 PM
CHEMIST

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757/S-022

Sanofi-Synthelabo, Inc.
Attention: David Ziering, Ph.D.
P.O. Box 5400
Princeton, NJ 08543-5400

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) Tablets

NDA Number: 20-757

Supplement number: S-022

Date of supplement: January 24, 2002

Date of receipt: January 25, 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 March 26, 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 Drug Products, 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 Drug Products, HFD-110
Attention: Division Document Room
1451 Rockville Pike
Rockville, Maryland 20852

If you have any questions, please call:

Mr. Edward Fromm
Regulatory Project Manager
(301) 594-5313

Sincerely yours,

/S/

Natalia A. Morgenstern
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/

Natalia Morgenstern
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