020757__S027

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757/S-027

Sanofi-Synthelabo
C/o Bristol-Myers Squibb Company
Attention: H. Leon Levinsky
P. O. Box 4000
Princeton, NJ 08543-4000

Dear Mr. Levinsky:

Please refer to your supplemental new drug application dated April 15, 2003, received April 18, 2003, 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 a revision in [ ]: Irbesartan Tablets Assay Method [ ] Irbesartan Tablets - Assay [ ]

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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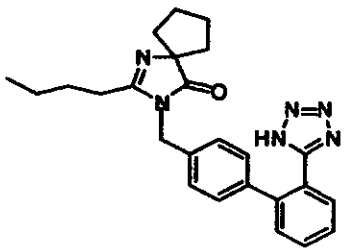
/s/

Kasturi Srinivasachar
10/9/03 05:11:07 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 4000 Princeton, NJ 08543-4000		4. **Supplement(s)** **Number(s) Date(s)** SCS-027 04/15/03
5. **Drug Name** Avapro	6. **Nonproprietary Name** Irbesartan	7. **Amendments &** Other (reports, etc) - Dates
7. **Supplement Provides for:** CHANGES BEING EFFECTED-in 30 Days revision in [ ] Irbesartan Tablets Assay Method —— Irbesartan Tablets - [ ]		
9. **Pharmacological Category** Angiotensin II Receptor Antagonist/Hypertension	10. **How Dispensed** /x/ RX /__/ OTC	11. **Related IND(s)/ NDA(s)/DMF(s)**
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:** As per "Guidance for Industry - Changes to an Approved NDA or ANDA, November 1999", the changes [ ] method qualifies for a CBE supplement.		
17. **Conclusions and Recommendations:** The supplement provides sufficient information to support the change in [ ] method for the assay of irbesartan and since irbesartan and all [ ] are detected [ ] The supplement may be approved.		
18. **REVIEWER:** Ramsharan D. Mittal		

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

_____ § 552(b)(5) Deliberative Process

_____ § 552(b)(5) Draft Labeling

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/s/

Ramsharan Mittal
10/8/03 11:09:21 AM
CHEMIST

Kasturi Srinivasachar
10/9/03 01:35:13 PM
CHEMIST

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-757/S-027

CBE-30/CBE-0 SUPPLEMENT

Sanofi-Synthelelabo c/o Bristol Myers Squibb
Attention: Mr. H. Leon Levinsky
P.O. Box 4000
Princeton, NJ 08534-4000

Dear Mr. Levinsky:

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, 300 mg Tablets

NDA Number: 20-757

Supplement number: 027

Date of supplement: April 15, 2003

Date of receipt: April 18, 2003

This supplemental application, submitted as "Supplement - Changes Being Effected in 30 days," proposes to [ ] Irbesartan tablets assay method. — Irbesartan Tablets - [ ]

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on June 17, 2003, in accordance with 21 CFR 314.101(a). If the application is filed, the user fee goal date will be October 18, 2003.

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, 5002
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, 5002
1451 Rockvill Pike, Woodmont II
Rockville, Maryland 20852

If you have any questions, please call:

Mr. Edward Fromm
Regulatory Project Manager
(301) 549-5332

Sincerely,

/S/
{See appended electronic signature page}

Zelda McDonald
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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