020757—S009
NDA 20-757/S-009

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

Dear Dr. Torre:

Please refer to your supplemental new drug application (NDA) dated July 9, 1999, received July 13, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Avapro (irbesartan) Tablets, 75 mg, 150 mg and 300 mg.

The supplemental application provides for the use of an alternative □
that □

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.

Sincerely yours,

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

CC:
Bristol-Myers Squibb Company
Attention: Melody Brown
P.O. Box 5400
Princeton, NJ 08543-5400
CC:  
Original NDA 20-757/S-009  
HFD-110/Division File  
HFD-110/DRoeder  
HFD-110/RMittal  
HFD-95  
DISTRICT OFFICE  
HFD-810/Jsimmons  
Init. by: Ksrinivasachar  
Drafted by: SO/11/2/99

Approval Date: 9/30/97

APPROVAL
DIVISION OF CARDIO-RENAL DRUG PRODUCTS
Review of Chemistry, Manufacturing, and Controls

<table>
<thead>
<tr>
<th>CHEMIST'S REVIEW</th>
<th>1. ORGANIZATION</th>
<th>2. NDA Number</th>
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<td>HPD - 110</td>
<td>20-757</td>
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<tr>
<th>3. Name and Address of Applicant (City &amp; State)</th>
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<tbody>
<tr>
<td>Bristol Myers Squibb Company</td>
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<tr>
<td>P. O. Box 4000</td>
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<td>Princeton, NJ 08543-4000</td>
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<th>4. Supplement(s)</th>
<th>Number(s) Date(s)</th>
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<tr>
<th>5. Drug Name</th>
<th>6. Nonproprietary Name</th>
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<tbody>
<tr>
<td>Avapro</td>
<td>Irbesartan</td>
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7. Supplement Provides for: SPECIAL SUPPLEMENT - CHANGES BEING EFFECTED

The changes being effected date is August 9, 1999.

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<th>9. Pharmacological Category</th>
<th>10. How Dispensed</th>
<th>11. Related IND(s)/NDA(s)/DMF(s)</th>
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<tr>
<td>Angiotensin II Receptor</td>
<td>[X] RX</td>
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<td>Antagonist/Hypertension</td>
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<th>12. Dosage Form(s)</th>
<th>13. Potency(ies)</th>
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<td>Tablets</td>
<td>75 mg, 150mg, and 300 mg.</td>
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14. Chemical Name and Structure

2-Butyl-1-[(2'-(1H-tetrazol-5-yl)biphenyl-4-yl)methyl]-1,3-diazaspiro[4.4]non-1-en-4-one.

15. Records/Reports

[ ] Yes [ ] No

[ ] Yes [ ] No


17. Conclusions and Recommendations:

Satisfactory and recommended for approval.

18. REVIEWER

<table>
<thead>
<tr>
<th>Name</th>
<th>Signature</th>
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<tr>
<td>Ramsharan D. Mittal</td>
<td>[Signature]</td>
<td>10/27/99</td>
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19. Distribution:

/ / Original Jacket / / Reviewer / / Division File / / CSO
Application: NDA 20757/009
Stamp: 13-JUL-1999
Regulatory Due: 13-NOV-1999
Applicant: SANOFI PHARMS
         90 PARKE AVE
         NEW YORK, NY 10016
Priority: 1S
Org Code: 110

Action Goal: District Goal: 09-OCT-1999
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: THIS LEVEL 2 CBE SUPPLEMENT PERTAINS TO AN ALTERNATIVE CHANGE WILL BE EFFECTIVE AUG 8, 1999. (on 19-JUL-1999 by F. ZIELINSKI (HFD-110) 301-594-5300)
FDA Contacts: R. MITTAL (HFD-110) 301-594-5353, Review Chemist
              K. SRINIVASACHAR (HFD-110) 301-594-5376, Team Leader

Overall Recommendation: ACCEPTABLE on 19-JUL-1999 by S. FERGUSON (HFD-324) 301-827-0062

Establishment: 1819504
BRISTOL MYERS SQUIBB CO
2400 WEST LLOYD EXPY
EVANSVILLE, IN 477210001

DMF No: AADA:
Responsibilities: INTERMEDIATE MANUFACTURER
Profile: TCM
OAI Status: NONE

Estab. Comment:

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