

**CENTER FOR DRUG EVALUATION AND RESEARCH**

**APPROVAL PACKAGE FOR:**

**APPLICATION NUMBER**

**NDA 20-757/S-021**

**Chemistry Review(s)**

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

<b>CHEMIST'S REVIEW</b>	<b>1. ORGANIZATION</b> HFD - 110	<b>2. NDA Number</b> 20-757
<b>3. Name and Address of Applicant (City &amp; State)</b>  Bristol-Myers Squibb Company P. O. Box 5400 Princeton, NJ 08543-5400		<b>4. Supplement(s)</b>  <b>Number(s) Date(s)</b> SE1-021 08/03/01 (Original) 03/25/02 resubmission
<b>5. Drug Name</b>  Avapro	<b>6. Nonproprietary Name</b>  Irbesartan	<b>7. Amendments &amp; Other (reports, etc) - Dates</b>  May 17, 2002
<b>7. Supplement Provides for:</b>  the treatment of hypertensive patients with type 2 diabetic renal disease.		
<b>9. Pharmacological Category</b>  Angiotensin II Receptor Antagonist/Hypertension	<b>10. How Dispensed</b>  <input checked="" type="checkbox"/> RX <input type="checkbox"/> OTC	<b>11. Related IND(s)/ NDA(s)/DMF(s)</b>  NDA 20-758
<b>12. Dosage Form(s)</b>  Tablets	<b>13. Potency(ies)</b> 75 mg, 150mg, and 300 mg.	
<b>14. Chemical Name</b>  2-Butyl-3-[(2'-(1H-tetrazol-5-yl)biphenyl-4-yl)methyl]-1,3-diazaspiro[4.4]non-1-en-4-one.		<b>15. Records/Reports Current</b>  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No  Reviewed  <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
<b>16. Comments:</b>  This is an efficacy supplement and except Environmental Assessment (May 17, 2002), no new CMC information was provided.		
<b>17. Conclusions and Recommendations:</b>  Categorical exclusion for environmental assessment is granted because the amount of increase in use of the active moiety is not significant. The supplement may be approved from the CMC standpoint.		
<b>18. REVIEWER</b>  Ramsharan D. Mittal		

Redacted 1

pages of trade

secret and/or

confidential

commercial

information

-----  
**This is a representation of an electronic record that was signed electronically and  
this page is the manifestation of the electronic signature.**  
-----

/s/

-----  
Ramsharan Mittal  
5/29/02 06:21:36 PM  
CHEMIST

Kasturi Srinivasachar  
5/29/02 07:19:02 PM  
CHEMIST