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RESEARCH**

**APPLICATION NUMBER: 21-071/001**

**CHEMISTRY REVIEW(S)**



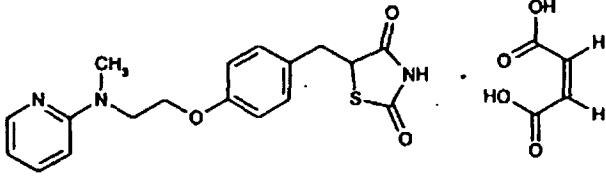

**NDA 21-071/S-001**

**Avandia® (rosiglitazone maleate) Tablets**

**Item 3.D Chemistry, Manufacturing, and Controls Summary**

**[Available by cross-reference to NDA 21-071 dated November 24, 1998]**

**APPEARS THIS WAY  
ON ORIGINAL**

CHEMIST'S REVIEW		
<b>Organization CDER/HFD-510</b> Division of Metabolism and Endocrine Drug Products		<b>NDA # 21-071</b> Approved: 25-MAY-1999
<b>Name and Address of Applicant:</b> SmithKline Beecham Pharmaceuticals 1250 South Collegeville Road Mail Code UP4340, PO Box 5089 Collegeville, PA 19426-0989 Phone: (610) 917-5907		<b>Supplement SEI-001</b> Doc. 02-JUN-1999 Rec. 03-JUN-1999 <b>Name Of The Drug</b> Avandia® Tablets <b>Nonproprietary Name</b> Rosiglitazone maleate Tablets
<b>Supplement provides the information to support the use of Avandia® (Rosiglitazone maleate) Tablets in combination with sulfonylurea for the treatment of patients with Type 2 diabetes mellitus.</b>		<b>New Correspondence</b> --
<b>Pharmacological Category</b> Hypoglycemic Agent. Adjunct to diet to improve glycemic control in patients with NIDDM whose hyperglycemia cannot be managed by diet alone.	<b>How Dispensed</b> Oral Rx	<b>Supporting Documents</b> -
<b>Dosage Form</b> Tablets	<b>Potencies</b> 2.0-, 4.0- and 8.0-mg	
<b>Chemical Name and Structure</b> Rosiglitazone maleate $C_{18}H_{19}N_3O_3S \cdot C_4H_4O_4$ $MW = 357.4 + 116.1 = 473.5$		
		
(±)-5[[4-[2-Methyl-2-(pyridinylamino)ethoxy]phenyl]methyl]-2,4-thiazolidinedione (Z)-2-butenedioate (1:1)		
<b>Comments:</b> Avandia was approved for the treatment of Type 2 diabetes mellitus on May 25, 1999 as monotherapy and in combination with metformin. This [efficacy] Supplement details the information to support the use of Avandia® (Rosiglitazone maleate) Tablets in combination with sulfonylurea for the treatment of patients with Type 2 diabetes mellitus. The drug substance and drug product remain unchanged. The appropriateness of the data to support the proposed therapeutical use will be evaluated by other disciplines. No new environmental assessment information is required.		
<b>Conclusions and Recommendations</b> There are no changes regarding Chemistry, Manufacture and Controls of neither the drug substance nor the drug product submitted under this efficacy supplement. Consequently, from the chemistry point of view, this supplement can be approved.		
<b>Reviewer Name (and signature)</b> Xavier Ysern, PhD  R/D Init.		<b>Date Completed:</b> 07-JAN-2000  <b>filename:</b> _____
<b>DISTRIBUTION:</b> Original: NDA 21-071 cc: HFD-510 Division File/ JWeber / SMoore/ XYsern		

AP  
 [S] 1/7/00