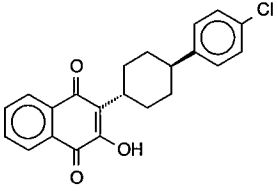
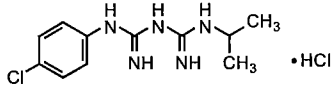


CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-078 / S-004

CHEMISTRY REVIEW(S)

SUPPLEMENTAL NDA CHEMIST'S REVIEW				1. ORGANIZATION: HFD-590		2. NDA NUMBER: 21-078	
3. NAME AND ADDRESS OF APPLICANT: (City and State) GlaxoSmithKline One Franklin Plaza P.O. Box 7929 Philadelphia, PA 19101				4. SUBMISSION TYPE: Prior Approval			
				5. SUPPLEMENT(S):			
				NUMBER(S): SCS-004 SCS-004 (BC)		DATE(S): 11-JAN-2002 08-MAY-2002	
6. NAME OF DRUG: Malarone™				7. NONPROPRIETARY NAME: atovaquone and proguanil hydrochloride			
8. SUPPLEMENT PROVIDES FOR: Registration of a dissolution method for atovaquone				9. AMENDMENTS/REPORTS:			
10. PHARMACOLOGICAL CATEGORY: Antimalarial		11. HOW DISPENSED: <input checked="" type="checkbox"/> Rx <input type="checkbox"/> OTC		12. RELATED IND/NDA/DMF(S):			
13. DOSAGE FORM(S): Tablets			14. POTENCY(IES): 250 mg atovaquone/100 mg proguanil and 62.5 mg atovaquone/25 mg proguanil				
15. CHEMICAL NAME AND STRUCTURE:				16. MEMORANDA:			
 <p>Atovaquone <i>trans</i>-2-[4-(4-Chlorophenyl)-cyclohexyl]-3-hydroxy-1,4-naphthalenedione</p>				 <p>Proguanil 1-(4-chlorophenyl)-5-isopropyl biguanide hydrochloride</p>			
17. COMMENTS: A:							
[]							
18. CONCLUSIONS AND RECOMMENDATIONS: From a CMC perspective, the method is acceptable. Final recommendations concerning approval will be made by the Biopharm reviewer.							
19. REVIEWER:		SIGNATURE:			DATE COMPLETED:		
Gene W. Holbert, Ph.D.					10-MAY-2002		
20. CONCURRENCE:							
Norman R. Schmuft, Ph.D.							
DISTRIBUTION:	X	Original NDA	X	HFD-590: NSchmuft	X	HFD-590: MBourg	
	X	Division File HFD-590	X	HFD-590: GHolbert	X	HFD-830: CChen	

WITHHOLD 3 **PAGE(S)**

B4

Chemistry Review

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

/s/

Gene Holbert
5/13/02 09:59:16 AM
CHEMIST

Norman Schmuff
5/13/02 02:50:51 PM
CHEMIST