

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-790 / S-002

CHEMISTRY REVIEW(S)

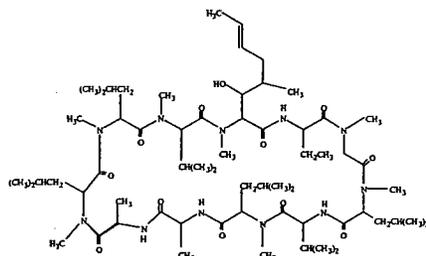
SUPPLEMENT REVIEW

DIVISION OF ANTI-INFLAMMATORY, ANALGESIC, & OPHTHALMIC DRUG PRODUCTS

Review of Chemistry, Manufacturing, and Controls

Chemistry Review # 1	1. Division HFD-550	2. NDA Number 50-790
3. Name and Address of Applicant Allergan 2525 Dupont Drive PO Box 19534 Irvine, CA	4. Supplement: SCS Number Letter Date Stamp Date Due Date S-002 6/27/03 6/30/03	
5. Name of Drug Restasis	6. Nonproprietary Name cyclosporine	
7. Supplement Provides for: Provide additional _____ of finished drug product. This is a CBE 30 supplement		8. Amendment(s) SCS-002 BC, 7/29/03
9. Pharmacological Category Immunomodulator and anti-inflammatory agent	10. How Dispensed R	11. Related Documents
12. Dosage Form Emulsion	13. Potency(ies) 0.05 %	
14. Chemical Name and Structure see USAN		
15. Comments: The supplement requests approval for the addition of _____ _____ in amendment dated 7/29/03 Microbiologist recommended approval on the basis of product quality microbiology		
16. Conclusion: The supplement is recommended for approval from a chemistry, manufacturing, and control, standpoint.		
17. Name Su C. Tso	Signature	Date: Sept. 5, 2003
Concurrence Linda Ng, Ph.D., Team Leader		

Structure:



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Chemistry Review 1a

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/s/

Su Tso
9/10/03 04:22:18 PM
CHEMIST

chemist's review

Linda Ng
9/10/03 04:53:36 PM
CHEMIST
PM to prepare AP letter