

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-790 / S-002

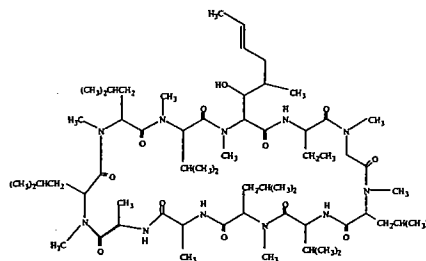
CHEMISTRY REVIEW(S)

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 <table border="1"> <tr> <th>Number</th> <th>Letter Date</th> <th>Stamp Date</th> <th>Due Date</th> </tr> <tr> <td>S-002</td> <td>6/27/03</td> <td>6/30/03</td> <td></td> </tr> </table>		Number	Letter Date	Stamp Date	Due Date	S-002	6/27/03	6/30/03	
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:



WITHHOLD 4 PAGE(S)

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this page is the manifestation of the electronic signature.**

/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