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APPLICATION NUMBER:

50-790 / S-002

MICROBIOLOGY REVIEW

Product Quality Microbiology Review

Consult Review for HFD-550

19 August 2003

NDA: 50-790/SCS-002

Drug Product Name:

Proprietary: RESTASIS™

Non-proprietary: cyclosporine ophthalmic emulsion

Drug Product Classification: ophthalmic

Review Number: 1

Subject of this Review:

Submission Date: 27 June 2003

Receipt Date: 30 June 2003

Consult Date: 01 July 2003

Date Assigned for Review: 30 July 2003

Applicant/Sponsor:

Name: Allergan

Address: 2525 DuPont Drive, P.O. box 19534, Irvine, CA 92623-9534

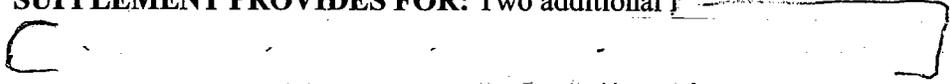
Representative: Elizabeth Bancroft

Telephone: (714) 246-4391

Name of Reviewer: Paul Stinavage

Conclusion: The application is recommended for approval on the basis of product quality microbiology.

Product Quality Microbiology Data Sheet

- A. 1. **TYPE OF SUPPLEMENT:** Changes Being Effected in 30 Days
2. **SUPPLEMENT PROVIDES FOR:** Two additional f 
3. **MANUFACTURING SITE:** _____
4. **DOSAGE FORM, ROUTE OF ADMINISTRATION AND STRENGTH/POTENCY:** 0.05% in unit dose form-fill-seal containers.
5. **METHOD(S) OF STERILIZATION:** _____
6. **PHARMACOLOGIC CATEGORY:** lacrimator

B. **SUPPORTING/RELATED DOCUMENTS:** (none)

C. **REMARKS:** 

This submission originally was NDA 21-023 and was reviewed by Dr. Bryan Riley of the Microbiology Team.

Executive Summary

I. Recommendations

- A. **Recommendation on Approvability** – The application is recommended for approval on the basis of product quality microbiology.
- B. **Recommendation on Phase 4 Commitments and/or Agreements, if Approvable**
Not applicable

II. Summary of Microbiology Assessments

- A. **Brief Description of the Manufacturing Processes that relate to Product Quality Microbiology**

- B. **Brief Description of Microbiology Deficiencies** – None

III. Administrative

- A. **Reviewer's Signature** _____
- B. **Endorsement Block**
Paul Stinavage/19 August 2003
P.H. Cooney/
- C. **CC Block**
cc:
Original NDA 50-790
HFD-550/Division File/NDA 50-790/L. Ng/L. Gorski

WITHHOLD 2 PAGE(S)

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

/s/

Paul Stinavage
8/25/03 05:34:18 AM
MICROBIOLOGIST
Two additional _____

Peter Cooney
8/27/03 01:29:09 PM
MICROBIOLOGIST