CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 21-023

MICROBIOLOGY REVIEW(S)



FEB 2 3 2000

REVIEW FOR HFD-550 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST'S REVIEW #4 OF NDA

February 2, 2000

- A. 1. <u>NDA</u> 21-023
 - SPONSOR Allergan, Inc.

2525 Dupont Circle P.O. Box 19534

Irvine, CA 92623-9534

- 2. PRODUCT NAMES: Cyclosporine
- 3. <u>DOSAGE FORM AND ROUTE OF ADMINISTRATION</u>: Vial Ophthalmic Emulsion
- 4. METHOD(S) OF STERILIZATION:
- 5. PHARMACOLOGICAL CATEGORY: Immunomodulator/Anti-Inflammatory Agent
- 6. DRUG PRIORITY CLASSIFICATION:
- B. 1. DATE OF INITIAL SUBMISSION: February 24, 1999
 - 2. <u>DATE OF AMENDMENT</u>: December 8, 1999
 - 3. RELATED DOCUMENTS: Microbiology reviews # 1, 2, and 3 of NDA 21-023
 - 4. ASSIGNED FOR REVIEW: December 20, 1999
- · C. <u>REMARKS</u>: This is a response to an "approvable letter" to the sponsor.



D. <u>CONCLUSIONS</u>: This application is recommended for approval on the basis of product quality microbiology.

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Bryan Riley, Ph.D.

cc:

Original NDA 21-023 HFD 550/Consult File HFD 550/L Gorski HFD 550/Tso HFD 805/Consult File

HFD 805/Consult File HFD 805/B. Riley

Drafted by: B. Riley, 2/2/00 R/D initialed by: P. Cooney,

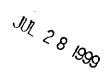
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REVIEW FOR HFD-550 OFFICE OF NEW DRUG CHEMISTRY MICROBIOLOGY STAFF MICROBIOLOGIST'S REVIEW # 3 OF NDA



July 28, 1999

A. 1. NDA 21-023, Original Amendment BI

SPONSOR

Allergan Inc.

2525 Dupont Drive P.O. Box 19534 Irvine, CA 93623-9534

- 2. PRODUCT NAMES: RESTASIS™ (Cyclosporine Ophthalmic Emulsion, 0.05%)
- 3. <u>DOSAGE FORM AND ROUTE OF ADMINISTRATION</u>: vial, Ophthalmic Emulsion
- 4. <u>METHOD(S) OF STERILIZATION</u>: ____
- 5. PHARMACOLOGICAL CATEGORY: Immunomodulator/Anti-Inflammatory Agent
- 6. DRUG PRIORITY CLASSIFICATION:
- B. 1. DATE OF INITIAL SUBMISSION: February 24, 1999.
 - 2. <u>DATE OF AMENDMENT</u>: July 13, 1999
 - 3. RELATED DOCUMENTS:
 - 4. ASSIGNED FOR REVIEW: July 21, 1999
- C. <u>REMARKS</u>: This review considers an amendment submitted by the sponsor to address microbiology deficiencies.



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