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RESEARCH**

APPLICATION NUMBER:
21-023

MICROBIOLOGY REVIEW(S)

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

FEB 23 2000

February 2, 2000

A. 1. NDA 21-023

SPONSOR Allergan, Inc.
2525 Dupont Circle
P.O. Box 19534
Irvine, CA 92623-9534

2. PRODUCT NAMES: Cyclosporine

3. DOSAGE FORM, AND ROUTE OF ADMINISTRATION: _____ 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. DATE OF AMENDMENT: December 8, 1999

3. RELATED DOCUMENTS: Microbiology reviews # 1, 2, and 3 of NDA 21-023

4. ASSIGNED FOR REVIEW: December 20, 1999

C. REMARKS: This is a response to an "approvable letter" to the sponsor.

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

LSI

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/B. Riley

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

LSI

2/23/2000

2 Page(s) Withheld

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

JUL 28 1999

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. DOSAGE FORM AND ROUTE OF ADMINISTRATION: _____ 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. DATE OF AMENDMENT: July 13, 1999

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: July 21, 1999

C. REMARKS: This review considers an amendment submitted by the sponsor to address microbiology deficiencies.

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