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. 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: [redacted] Vial, Ophthalmic Emulsion

4. METHOD(S) OF STERILIZATION: [redacted]

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.

/S/

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, /S/ 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: [redacted] vial, Ophthalmic Emulsion

4. METHOD(S) OF STERILIZATION: [redacted]

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.

D. CONCLUSIONS: This submission is approvable, pending resolution of Microbiological deficiencies. Please see "Microbiologist's List of Deficiencies" at the end of this review.

Bryan Riley, Ph.D. 7/28

7/28

cc:

HFD 550/Consult File
HFD 550/Tso
HFD 550/Boyd
HFD 550/Gorski
HFD 550/Ng
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 7/28/99
R/D initialed by: P. Cooney,

5 Page(s) Withheld

JUL 28 1999

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW # 2 OF NDA

July 28, 1999

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

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 12, 1999

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: July 21, 1999

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

D. CONCLUSIONS: This submission is not approvable. Please see "Microbiologist's List of Deficiencies".

Bryan Riley, Ph.D.

cc:

HFD 550/Consult File
HFD 550/Tso
HFD 550/Boyd
HFD 550/Gorski
HFD 550/Ng
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 7/28/99
R/D initialed by: P. Cooney,

2 Page(s) Withheld

MAY 17 1999

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW # 1 OF NDA

May 14, 1999

A. 1. NDA 21-023

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: Single-use vial, Ophthalmic Emulsion

4. METHOD(S) OF STERILIZATION: [redacted]

5. PHARMACOLOGICAL CATEGORY: Immunomodulator/Anti-Inflammatory Agent

6. DRUG PRIORITY CLASSIFICATION:

B. 1. DATE OF INITIAL SUBMISSION: February 24, 1999

2. DATE OF AMENDMENT:

3. RELATED DOCUMENTS:

4. ASSIGNED FOR REVIEW: March 15, 1999

C. REMARKS: The drug product is a sterile preservative-free, [redacted] emulsion containing 0.05% Cyclosporine. The drug product is packaged in a single-use vial (0.4 mL fill volume in 0.9 mL capacity) [redacted] manufactured as part of a [redacted]

D. CONCLUSIONS: This submission is approvable, pending resolution of microbiological issues. Please see "Microbiologist's List of Deficiencies".

/S/

Bryan Riley, Ph.D.

/S/

cc:

HFD 550/Consult File
HFD 550/Tso
HFD 550/Boyd
HFD 550/Gorski
HFD 550/Ng
HFD 805/Consult File
HFD 805/B. Riley

Drafted by: B. Riley, 5/14/99
R/D initialed by: P. Cooney,

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