

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number **20-963**

MICROBIOLOGY REVIEW(S)

Corislu 532

APR 7 1998

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 OF NDA 20-963
31 March 1998

A. 1. NDA 20-963

APPLICANT: Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099

2. PRODUCT NAME: Timolol Maleate Sterile Ophthalmic Gel
Forming Solution (0.25 and 0.5%)

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an ophthalmic solution for instillation into the eye.

4. METHODS OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is intended for use in lowering intraocular pressure in: patients with open-angle glaucoma, patients with aphakic glaucoma, some patients with secondary glaucoma, and other patients with elevated intraocular pressure who are at sufficient risk to require lowering of the ocular pressure.

B. 1. DATE OF INITIAL SUBMISSION: 16 February 1998

2. DATE OF AMENDMENT: (none)

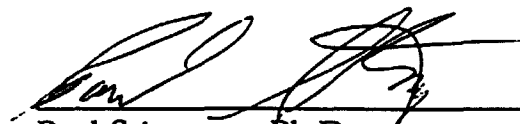
3. RELATED DOCUMENTS: (none)

4. ASSIGNED FOR REVIEW: 2 March 1998

C. REMARKS: The submission seeks approval for the product to be manufactured at the ASPEX site within Alcon's current campus in Fort Worth. The facility is known as the Alcon Sterile Production Expansion (ASPEX).

Alcon Labs, NDA 20-963, Timolol Maleate Opth. Soln., Microbiologist's Review #1 of NDA

D. CONCLUSIONS: The application is approvable pending resolution of microbiology concerns.


Paul Stinavage, Ph.D. 31 March 1998
PAC 4/7/98

cc: Original NDA 20-963
HFD-550/L. Gorski/A. Fenselau/H. Patel
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 31 March 1998
R/D initialed by P. Cooney

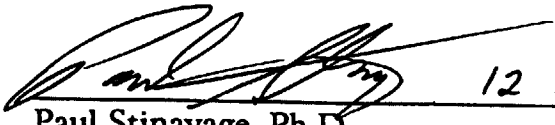
**APPEARS THIS WAY
ON ORIGINAL**

JUN 16 1998

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 OF NDA 20-963
12 June 1998

- A. 1. NDA 20-963
APPLICANT: Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099
2. PRODUCT NAME: Timolol Maleate Sterile Ophthalmic
Gel Forming Solution (0.25 and 0.5%)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an ophthalmic solution for instillation into the
eye.
4. METHODS OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE
INDICATION:
The product is intended for use in lowering intraocular pressure
in: patients with open-angle glaucoma, patients with aphakic
glaucoma, some patients with secondary glaucoma, and other
patients with elevated intraocular pressure who are at sufficient
risk to require lowering of the ocular pressure.
- B. 1. DATE OF INITIAL SUBMISSION: 16 February 1998
2. DATE OF AMENDMENT: 28 May 1998
3. RELATED DOCUMENTS: (none)
4. ASSIGNED FOR REVIEW: 9 June 1998
- C. REMARKS: The submission seeks approval for the product to be
manufactured at the ASPEX site within Alcon's current
campus in Fort Worth. The facility is known as the Alcon
Sterile Production Expansion (ASPEX).

D. CONCLUSIONS: The application is approvable pending resolution of microbiology concerns.


Paul Stinavage, Ph.D. 12 June 1998

JAC C/14/98

cc: Original NDA 20-963
HFD-550/L. Gorski/R. Uppoor/H. Patel
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 12 June 1998
R/D initialed by P. Cooney

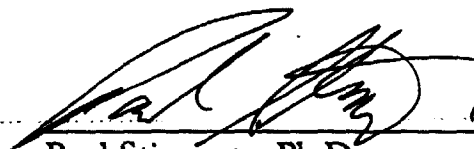
APPEARS THIS WAY
ON ORIGINAL

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGISTS' REVIEW #3 OF NDA 20-963
16 September 1998

- A. 1. NDA 20-963
APPLICANT: Alcon Laboratories, Inc.
6201 South Freeway
Fort Worth, TX 76134-2099
2. PRODUCT NAME: Timolol Maleate Sterile Ophthalmic
Gel Forming Solution (0.25 and 0.5%)
3. DOSAGE FORM AND ROUTE OF ADMINISTRATION:
The product is an ophthalmic solution for instillation into the
eye.
4. METHODS OF STERILIZATION:
5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE
INDICATION:
The product is intended for use in lowering intraocular pressure
in: patients with open-angle glaucoma, patients with aphasic
glaucoma, some patients with secondary glaucoma, and other
patients with elevated intraocular pressure who are at sufficient
risk to require lowering of the ocular pressure.
- B. 1. DATE OF INITIAL SUBMISSION: 16 February 1998
2. DATE OF AMENDMENT: 2 September 1998
3. RELATED DOCUMENTS: (none)
4. ASSIGNED FOR REVIEW: 9 June 1998
- C. REMARKS: The amendment addresses concerns communicated in
Microbiologist's Review #2 dated 12 June 1998. The
material reviewed was faxed to the Review Microbiologist
by the Project Manager.

The submission seeks approval for the product to be manufactured at the ASPEX site within Alcon's current campus in Fort Worth. The facility is known as the Alcon Sterile Production Expansion (ASPEX).

D. CONCLUSIONS: The application is recommended for approval on the basis of sterility assurance.


16 September 1998
Paul Stinavage, Ph.D.
PAC 9/17/98

cc: Original NDA 20-963
HFD-550/L. Gorski/R. Uppoor/H. Patel
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 16 September 1998
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL