

MAY 10 1999

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #1 of NDA 21-009
3 May 1999

A. 1. NDA 21-009

APPLICANT: Allergan
2525 DuPont Drive
P.O. Box 19534
Irvine, CA 92623-9534

2. PRODUCT NAMES: Nedocromil Sodium 2% Ophthalmic Solution

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 indicated in the treatment of allergic conjunctivitis.

B. 1. DATE OF INITIAL SUBMISSION: 31 March 1999

2. DATE OF AMENDMENT: (none)

3. RELATED DOCUMENTS: IND/ _____
DMF's _____

4. ASSIGNED FOR REVIEW: 14 April 1999

C. REMARKS: The entire manufacturing, filling, packaging, release testing,
and on-going stability testing processes will be performed at
the _____

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

[Redacted]

APPEARS THIS WAY
ON ORIGINAL

[Redacted] /S/

3 May 1999

Paul Stinavage, Ph.D.

[Redacted] /S/ 5/10/99

cc: Original NDA 21-009
HFD-550/Div. File/L. Gorski/L. Ng
HFD-805/Consult File/Stinavage

Drafted by: P. Stinavage, 3 May 1999
R/D initialed by P. Cooney

APPEARS THIS WAY
ON ORIGINAL

REVIEW FOR HFD-550
OFFICE OF NEW DRUG CHEMISTRY
MICROBIOLOGY STAFF
MICROBIOLOGIST'S REVIEW #2 of NDA 21-009
17 August 1999

AUG 27 1999

A. 1. NDA 21-009

APPLICANT: Allergan
2525 DuPont Drive
P.O. Box 19534
Irvine, CA 92623-9534

2. PRODUCT NAMES: Nedocromil Sodium 2% Ophthalmic Solution

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

4. METHODS OF STERILIZATION:
[Redacted]

5. PHARMACOLOGICAL CATEGORY and/or PRINCIPLE INDICATION:
The product is indicated in the treatment of allergic conjunctivitis.

B. 1. DATE OF INITIAL SUBMISSION: 31 March 1999

2. DATE OF AMENDMENT: 16 July 1999 (Subject of this Review)

3. RELATED DOCUMENTS: IND's [Redacted]
DMF's [Redacted]

4. ASSIGNED FOR REVIEW: 21 July 1999

C. REMARKS: The entire manufacturing, filling, packaging, release testing, and on-going stability testing processes will be performed at the [Redacted]

