

**Division of Anti-inflammatory, Analgesic and Ophthalmic Drugs**  
**Review of Chemistry, Manufacturing, and Controls**

**NDA #:** 21-009

**REVIEW #** 1

**DATE REVIEWED:** 8/16/99

<u>SUBMISSION TYPE</u>	<u>DOCUMENT DATE</u>	<u>CDER DATE</u>	<u>ASSIGNED DATE</u>
Original	3/31/99	4/2/99	4/8/99
Amendment	4/16/99	4/19/99	4/28/99
Amendment	4/23/99	4/26/99	4/29/99
Amendment	7/16/99	7/19/99	7/26/99

**NAME & ADDRESS OF APPLICANT:**

Allergan Inc.  
2525 Dupont Drive  
P. O. Box 19534  
Irvine, CA 92623

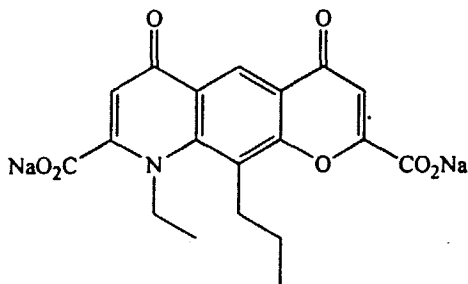
**DRUG PRODUCT NAME**

Proprietary: Abrevia  
Established: Nedocromil sodium  
Code Name/#: 59002KP & AGN 195095-Z2  
Chem.Type/Ther.Class: 3P

**PHARMACOL. CATEGORY:** Anti-inflammatory & mast cell stabilizer  
**DOSAGE FORM:** Solution  
**STRENGTHS:** 2%  
**ROUTE OF ADMINISTRATION:** Topical/ocular 1-2 drops twice a day  
**DISPENSED:**  Rx  OTC

**CHEMICAL NAME, STRUCTURAL FORMULA, MOLECULAR FORMULA AND WEIGHT:**

**Chemical Structure**



**Usan Name:** Nedocromil Sodium (AGN 195059-Z2)

**Molecular Formula:** C<sub>19</sub>H<sub>15</sub>NNa<sub>2</sub>O<sub>7</sub>

**Molecular Weight:** 415.30

**IUPAC Chemical Name**

Disodium 9-ethyl-6,9-dihydro-4,6-dioxo-10-propyl-4H-pyranol[3,2-g] quinoline-2,8 dicarboxylate [redacted]

4,6-dioxo-1-ethyl-10-propyl-4H,6H-pyrano[3,2-g]quinoline-2,8-dicarboxylic acid disodium salt [redacted]

**SUPPORTING DOCUMENTS: pg. 176, vol. 1.1**

<b>File Type</b>	<b>File Owner</b>	<b>Reference For:</b>
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DMF

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**CONCLUSIONS & RECOMMENDATIONS:**

The application is approvable pending for the satisfactory responses to

- An acceptable trade name,
- The micro deficiencies,
- The chemistry deficiencies listed in the draft of the chemistry comments,
- A satisfactory CGMP inspection at drug product manufacturing facility

APPEARS THIS WAY  
ON ORIGINAL

cc:  
Orig. NDA 21-009  
HFD-550/Division File  
HFD-550/Tso  
HFDD-550/Gorski  
HFD-830/CWChen  
HFD-550/Dunbar  
HFD-550/Weir  
HFD-550/Ng.  
HFD-550/Chambers  
HFD-550/Rodriguez L

/S/

Chemist, HFD-550/830  
Su C. Tso, Ph.D.

/S/

Linda Ng, Ph.D.  
Chemistry Team Leader, HFD-550

8/24/99

APPEARS THIS WAY  
ON ORIGINAL

Molecular Formula:  $C_{19}H_{15}NNa_2O_7$

Molecular Weight: 415.30

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quinoline-2,8 dicarboxylate

4,6-dioxo-1-ethyl-10-propyl-4H,6H-pyrano[3,2-g]quinoline-2,8-  
dicarboxylic acid disodium salt

**SUPPORTING DOCUMENTS**

Chemistry review #1 dated 8/16/99

Chemistry review #2 dated 9/17/99

**REMARKS:**

Allergan proposed two new trade names in the 9/15/99 amendment. The trade name MURINE is not acceptable, but the trade name ALOCRIIL was found to be acceptable (report attached).

Allergan has revised the package insert according to the chemist's request which was faxed to the applicant on 8/11/99. The revision is acceptable, however the labeling as a whole will be re-visited later by the review team.

GMP inspection to the drug manufacturing site at \_\_\_\_\_  
was completed, Office of Compliance recommended for approval. Compliance report attached.

CONCLUSIONS & RECOMMENDATIONS:

The application is recommended for approval from a chemistry, manufacturing, and control standpoint.

The application may be approved for an expiration date of 24 months when stored at 4 - 25<sup>0</sup> C.

APPROB THIS WAY  
OR ORIGINAL

/S/

cc:  
Orig. NDA 21-009  
HFD-550/Division File  
HFD-550/Tso  
HFDD-550/Gorski  
HFD-830/CWChen  
~~HFD-550/Weir~~  
HFD-550/Weir  
HFD-550/Ng.  
HFD-550/Chambers  
HFD-550/Rodriguez L

Chemist, HFD-550/830  
Su C. Tao, Ph.D

/S/ 12/8/99  
Linda Ng, Ph.D.  
Chemistry Team Leader, HFD-550

APPROB THIS WAY  
OR ORIGINAL