ANDA 74-706

APR 29 1998

Advanced Remedies, Inc.
Attention: Hari Menon
72-6 Veronica Avenue
Somerset, NJ 08873

Dear Sir:

This is in reference to your abbreviated new drug application dated June 29, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Cromolyn Sodium Ophthalmic Solution USP, 4%.

Reference is also made to your amendments dated September 9, 1997; and February 27, April 6, and April 27, 1998.

We have completed the review of this abbreviated application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved. The Division of Bioequivalence has determined your Cromolyn Sodium Ophthalmic Solution, USP, 4% to be bioequivalent and, therefore, therapeutically equivalent to the listed drug (Opticrom Ophthalmic Solution of Allergan Pharmaceutical).

Under 21 CFR 314.70, certain changes in the conditions described in this abbreviated application require an approved supplemental application before the change may be made.

Post-marketing reporting requirements for this abbreviated application are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

We request that you submit, in duplicate, any proposed advertising or promotional copy which you intend to use in your initial advertising or promotional campaigns. Please submit all proposed materials in draft or mock-up form, not final print. Submit both copies together with a copy of the proposed or final printed labeling to the Division of Drug Marketing, Advertising, and Communications (HFD-240). Please do not use Form FD-2253 (Transmittal of Advertisements and Promotional Labeling for Drugs for Human Use) for this initial submission.

We call your attention to 21 CFR 314.81(b)(3) which requires that materials for any subsequent advertising or promotional campaign be submitted to our Division of Drug Marketing, Advertising, and Communications (HFD-240) with a completed Form FD-2253 at the time of their initial use.

Sincerely yours,

4/29/98

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

CROMOLYN SODIUM
OPHTHALMIC SOLUTION USP, 4%,
Sterile

Rev. 1/98

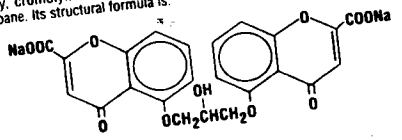
000700

APPROVED

APR 29 1998

**DESCRIPTION:** Each milliliter of Cromolyn Sodium Ophthalmic Solution USP, 4% contains 40 mg cromolyn sodium in purified water with 0.01% benzalkonium chloride to preserve and 0.1% EDTA (edetate disodium, USP) to stabilize the solution. Cromolyn sodium is a clear, colorless, sterile solution with a pH of 4.0-7.0. It is intended for topical administration to the eye.

Chemically, cromolyn sodium is the disodium salt of 1,3-bis(2-carboxychromon-5-yloxy)-2-hydroxypropane. Its structural formula is:




Mol.Wt. 512.34

$C_{23}H_{14}Na_2O_{11}$

Pharmacologic Category: Mast cell stabilizer.

**CLINICAL PHARMACOLOGY**

*In vitro* and *in vivo* animal studies have shown that cromolyn sodium inhibits the degranulation of sensitized mast cells which occurs after exposure to specific antigens. Cromolyn sodium acts by inhibiting the release of histamine and SRS-A (slow-reacting substance of anaphylaxis) from the mast cell.

Another activity demonstrated *in vitro* is the capacity of cromolyn sodium to inhibit the degranulation of non-sensitized rat mast cells by phospholipase A and the subsequent release of chemical mediators. Another study showed that cromolyn sodium did not inhibit the enzymatic activity of released phospholipase A on its specific substrate.

Cromolyn sodium has no intrinsic vasoconstrictor, antihistaminic or anti-inflammatory activity.

Cromolyn sodium is poorly absorbed. When multiple doses of cromolyn sodium ophthalmic solution are instilled into normal rabbit eyes, less than 0.07% of the administered dose of cromolyn sodium is absorbed into the systemic circulation (presumably by way of the eye, nasal passages, buccal cavity and gastrointestinal tract). Trace amounts (less than 0.01%) of the cromolyn sodium dose penetrate into the aqueous humor and clearance from this chamber is virtually complete within 24 hours after treatment is stopped.

In normal volunteers, analysis of drug excretion indicates that approximately 0.03% of cromolyn sodium is absorbed following administration to the eye.

A study on corneal epithelial wound healing in albino rabbits failed to demonstrate any significant difference in the rate of corneal re-epithelialization between cromolyn sodium ophthalmic solution, sterile saline solution, no treatment and an ophthalmic corticosteroid.

**INDICATIONS AND USAGE**

Cromolyn sodium ophthalmic solution is indicated in the treatment of vernal keratoconjunctivitis, vernal conjunctivitis, and vernal keratitis.

Symptomatic response to therapy (decreased itching, tearing, redness and discharge) is usually evident within a few days, but longer treatment for up to six weeks is sometimes required. Once symptomatic improvement has been established, therapy should be continued for as long as needed to sustain improvement.

If required, corticosteroids may be used concomitantly with cromolyn sodium ophthalmic solution.

Users of soft (hydrophilic) contact lenses should refrain from wearing lenses while under treatment with cromolyn sodium ophthalmic solution (see **CONTRAINDICATIONS**). Wear can be resumed within a few hours after discontinuation of the drug.

**CONTRAINDICATIONS**

Cromolyn sodium ophthalmic solution is contraindicated in those patients who have shown hypersensitivity to cromolyn sodium or to any of the other ingredients.

As with all ophthalmic preparations containing benzalkonium chloride, patients are advised not to wear soft contact lenses during treatment with cromolyn sodium ophthalmic solution.

**PRECAUTIONS**

**General**: Patients may experience a transient stinging or burning sensation following application of cromolyn sodium ophthalmic solution.

The recommended frequency of administration should not be exceeded. The dose for adults and children is 1 or 2 drops in each eye 4 to 6 times a day at regular intervals.

**Carcinogenesis, Mutagenesis, Impairment of Fertility**: Long term studies in mice (12 months intraperitoneal treatment followed by six months observation), hamsters (12 months intraperitoneal treatment followed by 12 months observation), and rats (18 months subcutaneous treatment) showed no neoplastic effect of cromolyn sodium.

No evidence of chromosomal damage or cytotoxicity was obtained in various mutagenesis studies.

No evidence of impaired fertility was shown in laboratory animal reproduction studies.



**Pregnancy: Teratogenic effects: Pregnancy Category B**. Reproduction studies with cromolyn sodium administered parenterally to pregnant mice, rats and rabbits in doses up to 338 times the human clinical doses produced no evidence of fetal malformations. Adverse fetal effects (increased resorption and decreased fetal weight) were noted only at the very high parenteral doses that produced maternal toxicity. There are, however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

**Nursing Mothers:** It is not known whether cromolyn sodium is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when cromolyn sodium is administered to a nursing woman.

**Pediatric Use:** Safety and effectiveness in pediatric patients below the age of 4 years have not been established.

**ADVERSE REACTIONS**

The most frequently reported adverse reaction, attributed to the use of cromolyn sodium ophthalmic solution, on the basis of reoccurrence following readministration, is transient ocular stinging or burning upon instillation.

The following adverse reactions have been reported as infrequent events. It is unclear whether they are attributable to the drug:

Conjunctival injection
Watery eyes
Itchy eyes
Dryness around the eye
Puffy eyes
Eye irritation
Styes

**DOSAGE AND ADMINISTRATION**

The dose for adults and children is 1 or 2 drops in each eye 4 to 6 times a day at regular intervals. One drop contains approximately 1.6 mg cromolyn sodium.

Patients should be advised that the effect of cromolyn sodium ophthalmic solution therapy is dependent upon its administration at regular intervals, as directed.

**HOW SUPPLIED**

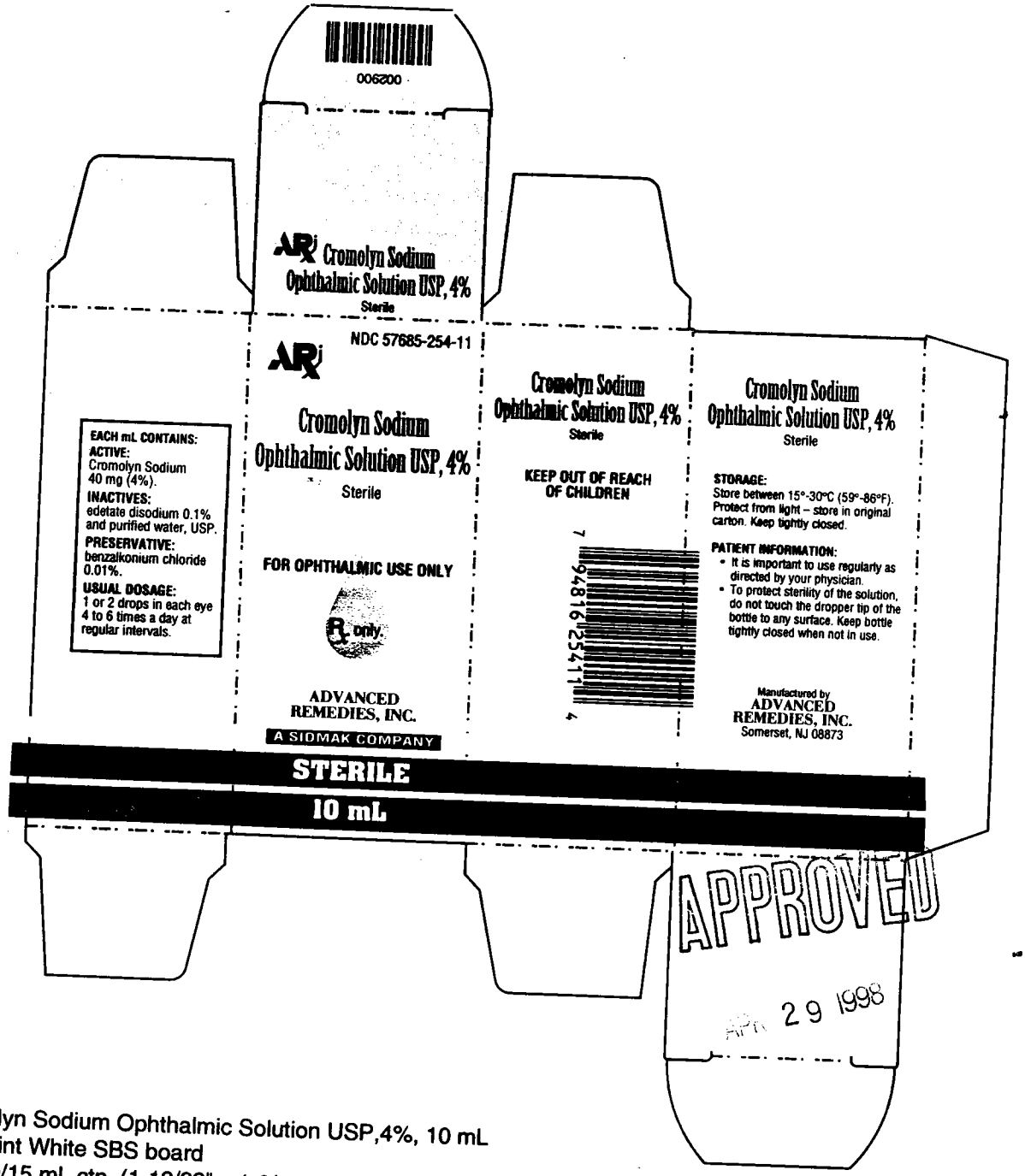
Cromolyn Sodium Ophthalmic Solution USP, 4% is supplied as 10 mL of solution in an opaque polyethylene bottle with a controlled dropper tip.

**Storage:** Keep tightly closed and out of the reach of children. Store between 15° - 30°C (59° - 86°F) and protect from light - store in original carton.

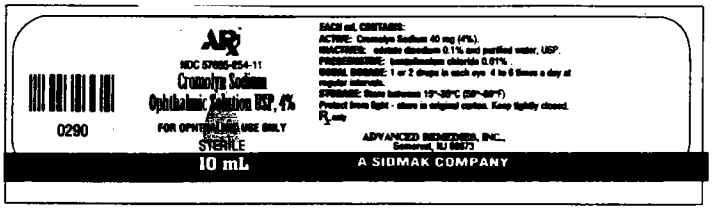
℞ only.

Manufactured By:
ADVANCED REMEDIES, INC.
Somerset, NJ 08873

Rev. 1/98



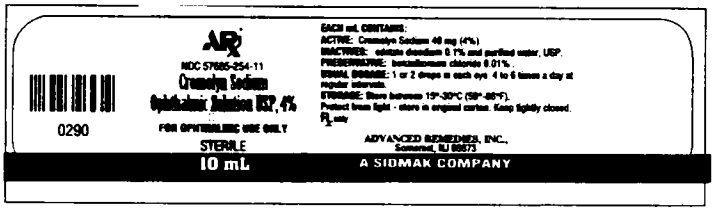

m: Cromolyn Sodium Ophthalmic Solution USP,4%, 10 mL
ɔck: 16 point White SBS board
:e: new 10/15 mL ctn. (1-13/32" x 1-9/32" x 3-3/16")
lors: Pantone yellow, Match Sidmak Red, black, PMS 400 gray, Pantone Proces Blue C
de on flap - Code 128 - # 002900
C # 57685-254-11
C code: 7 94816-254-11




Item: Cromolyn Sodium Label Size: 13/16" x 3-5/8", 10 mL
Stock:
Adhesive:
Colors: PMS Match Sidmak Red, PMS 400 Gray, Black, Pantone Process Blue
Varnish: Leave 3/8" area on right unvarnished for hot stamping
Code: Interweaved 2 of 5, # 0290, NDC #57685-254-11
Printer to order code to meet his requirements and the following specs
Ratio (Thick bar to thin bar) 3:1
Height of code 3/16"
Narrow bar = 8 mil.
Quiet Zone around code: 1/16"
HRC Height = .055" (for number under code)

Area on left side of label which will be wrapped under: 5/8"
Area on right hand side of label for hot stamping Lot number and Expiration date: 3/8"

APPROVED
29 1998

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Narrow bar = 8 mil.
Quiet Zone around code: 1/16"
HRC Height = .055" (for number under code)

Area on left side of label which will be wrapped under: 5/8"
Area on right hand side of label for hot stamping Lot number and Expiration date: 3/8"

APPROVED
29 1998

# APPROVAL PACKAGE SUMMARY FOR 74-706

ANDA: 74-706

FIRM: Advanced Remedies, Inc.

DRUG: Cromolyn Sodium

DOSAGE: sterile ophthalmic solution

STRENGTH: 40 mg/mL (4%)

CGMP STATEMENT/EIR UPDATE STATUS: EER is Acceptable on 2/24/98.

BIO STUDY/BIOEQUIVALENCE STATUS: Bioequivalence waiver was granted 12/5/95.

METHODS VALIDATION: The drug product is compendial

STABILITY: The firm has provided satisfactory 3 months accelerated stability data at 40°C.

LABELING REVIEW STATUS: Labeling is satisfactory 3/9/98

STERILIZATION VALIDATION: The microbiology portion is satisfactory 3/17/98.

BATCH SIZES: The firm has submitted the master formula and manufacturing procedures for the maximum batch size and copy of the executed batch record lot PD95-010. The firm will be using same drug substance manufacture . The DMF is satisfactory. Also using same manufacturing procedures and equipment.

COMMENTS: The application is approvable.

REVIEWER: Nashed E. Nashed, Ph.D. DATE: 3/20/98 3/26/98 4/16/98

SUPERVISOR: Paul Schwartz, Ph.D. 3/20/98 4/16/98

X:\NEW\FIRMSAM\ADVANREM\LTRS&REV\74x706.SUM

1. CHEMISTRY REVIEW NO. 3

2. ANDA # 74-706

3. NAME AND ADDRESS OF APPLICANT

Advanced Remedies, Inc.
72-6 Veronica Ave.
Somerset, NJ 08873

4. LEGAL BASIS FOR SUBMISSION

The firm indicated that there are no patents that claim the use of the listed drug. In the firm opinion and to the best knowledge the reference listed drug is not entitled to a period of marketing exclusivity.

5. SUPPLEMENT(s)

N/A

6. PROPRIETARY NAME

N/A

7. NONPROPRIETARY NAME

Cromolyn sodium

9. AMENDMENTS AND OTHER DATES:

Original 6/29/95
Amendment 9/5/95
Amendment 9/25/96
Amendment 9/9/97
Amendment 2/27/98
Amendment 4/6/98

10. PHARMACOLOGICAL CATEGORY

Treatment of vernal keratoconjunctivitis

11. Rx or TOC

Rx

12. RELATED IND/NDA/DMF(s)

13. DOSAGE FORM

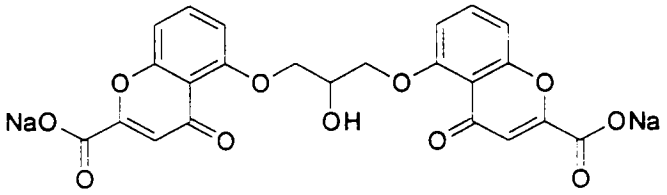
Sterile Ophthalmic Solution

14. POTENCY

40 mg/mL

15. CHEMICAL NAME AND STRUCTURE

Cromolyn Sodium. $C_{23}H_{14}Na_2O_{11}$. 512.34. 4*H*-1-Benzopyran-2-carboxylic acid, 5,5'-[(2-hydroy-1,3-propanediyl)bis(oxy)]bis[4,-oxo-, disodium salt]. 15826-37-6.). USP 23, page 430.




17. COMMENTS

The microbiology review is satisfactory 3/17/98

18. CONCLUSIONS AND RECOMMENDATIONS

The application is approvable.

19. REVIEWER: DATE COMPLETED:

Nashed E. Nashed, Ph.D. 4/15/98

Supervisor: Paul Schwartz, Ph.D.

cc: ANDA 74-706
Division File
Field Copy

Endorsements:

HFD-627/NNashed 4/15/98
HFD-627/PSchwartz/ 4/15/98
X:\NEW\FIRMSAM\ADVANREM\LTRS&REV\74x706.4
F/t by: gp

# OFFICE OF GENERIC DRUGS, HFD-620
## Microbiologist's Review #3
## March 16, 1998

A. 1. **ANDA** 74-706

APPLICANT Advanced Remedies

2. PRODUCT NAME: Cromolyn Sodium Ophthalmic Solution USP, 4%

3. DOSAGE FORM AND ROUTE OF ADMINISTRATION: Topical Ophthalmic Solution

4. METHOD(S) OF STERILIZATION:

5. PHARMACOLOGICAL CATEGORY: Mast-cell Stabilizer

B. 1. DATE OF INITIAL SUBMISSION: June 29, 1995
(Received on 7/7/95)

2. DATE OF AMENDMENT: September 9, 1997
(Received September 10, 1997)
**Subject of this Review**

3. RELATED DOCUMENTS: None

4. ASSIGNED FOR REVIEW: 3/13/98

C. REMARKS: The subject amendment provides for the response to the microbiology deficiencies in the correspondence dated February 7, 1997.

D. CONCLUSIONS: The submission is recommended for approval on the basis of sterility assurance. Specific comments are provided in "E. Review Notes"

3/16/98

Andrea S. High, Ph. D.

cc: Original **ANDA**
Duplicate ANDA
Division Copy
Field Copy
Drafted by A. High, HFD 620 x:wp\microrev\74-706a3
Initialed by R. Patel

ANDA 74-706

Advanced Remedies, Inc.
Attention: Hari Menon
72-6 Veronica Avenue
Someset NJ 08873

DEC 22 1995

Dear Sir:

Reference is made to your abbreviated new drug application dated June 29, 1995, submitted pursuant to Section 505 (j) of the Federal Food, Drug and Cosmetic Act for Cromolyn Sodium Ophthalmic Solution USP, 4%.

The following comments pertain only to bioequivalency issues in the June 29, 1995 submission.

> The Division of Bioequivalence has completed its review and has no further questions at this time.

Please note that the bioequivalency comments expressed in this letter are preliminary. The above bioequivalency comments may be revised after review of the entire application, upon consideration of the chemistry, manufacturing and controls, microbiology, labeling or other scientific or regulatory issues. A revised determination may require additional information and/or studies, or may conclude that the proposed formulation is not approvable.

Sincerely yours,

Keith K. Chan, Ph.D.
Director, Division of Bioequivalence
Office of Generic Drugs
Center for Drug Evaluation and Research

DEC 5 1995

Cromolyn Sodium
4% ophthalmic solution
ANDA #74-706
Reviewer: James D. Henderson
File: 74706W.695

Advanced Remedies, Inc.
Somerset, NJ
Submitted:
June 29, 1995

# REVIEW OF A WAIVER REQUEST

**Background:**

The sponsor has submitted an ANDA for its test product cromolyn sodium 4% ophthalmic solution and is requesting waiver of in vivo demonstration of bioequivalence. The reference listed drug (RLD) is Opticrom® Ophthalmic Solution (NDA #18-155, approved 10/3/84, Fisons).

**Comments:**

1. The test product is an ophthalmic solution which is applied topically for intended local therapeutic effect. The test product and RLD are identical with regard to indications, dosage form (ophthalmic drops), active ingredient (cromolyn sodium), route of administration (topical), and strength (4%).

2. Comparative formulations of the test product and RLD are shown in Table 1. The formulations appear to be qualitatively (Q1) and quantitatively (Q2) identical.

3. The Interim Inactive Ingredients Policy (11/17/94) states that an ophthalmic solution with the same Q1 and Q2 as the RLD shall be granted a waiver of in vivo BE study in accordance with 21 CFR 320.22(b)(1).

**Recommendation:**

The Division of Bioequivalence agrees that the information submitted by Advanced Remedies demonstrates that cromolyn sodium ophthalmic solution 4% falls under 21 CFR Section 320.22(b)(1) of the Bioavailability/Bioequivalence Regulations. The waiver of <u>in vivo</u> bioequivalence study for the test product cromolyn sodium ophthalmic solution 4% is granted. From the bioequivalence point of view, the test product cromolyn sodium ophthalmic solution 4% is deemed bioequivalent to Opticrom® 4% Ophthalmic Solution manufactured by Fisons.

James D. Henderson, Ph.D.
Review Branch II
Division of Bioequivalence

**Table 1 - Comparative Formulations of the Test Product and RLD**



| Ingredient | Test Product (amount/mL) | RLD[1] (amount/mL) |
|---|---|---|
| cromolyn sodium | 40 mg | 40 mg |
| edetate disodium | 1 mg | 1 mg (0.1%) |
| benzalkonium chloride | 0.1 mg[2] (0.01%) | 0.1 mg (0.01%) |
| purified water | qs | qs |

1 Labeling approved 6/11/93: clear, colorless, sterile solution with pH 4.0-7.0. The proposed labeling for the test product contains the same information.

ADVANCED REMEDIES, INC.
72-6 VERONICA AVENUE
SOMERSET, NJ 08873
(908) 846-8066 • FAX (908) 846-7952

505(j)(2)(A) acceptable for filing
6/27/95
7/27/95

June 29, 1995

Dr. Roger L. William, Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
5600 Fishers Lane
Rockville, MD 20857

Re: **Abbreviated New Drug Application For Cromolyn Sodium Ophthalmic Solution USP, 4% STERILE.**

Dear Dr. William:

Pursuant to 21 CFR, Section 314.50, Advanced Remedies, Inc., located at 72-6 Veronica Avenue, Somerset, NJ 08873, is hereby submitting its Abbreviated New Drug Application for the drug product, Cromolyn Sodium Ophthalmic Solution USP, 4% Sterile, for your review. The data demonstrating that the process is capable of providing "Sterility Assurance" is included in section XI 1a of this application.

We are submitting a Review Copy of the application, contained in red jackets, comprising two (2) volumes and a Bioequivalency/ Bioavailability section contained in an orange jacket.

We are also submitting an Archival Copy of the application, contained in blue jackets, comprising two (2) volumes.

In addition, we are submitting the field copy which is a true copy of the technical section contained in the Archival and Review copies of this ANDA application to the District office.

Your expeditious review of our application is greatly appreciated. If you require any further information, please contact the undersigned at the above address or at (908) 846-8066.

Thanking you in advance.

Sincerely yours,

Hari Menon
President
Advanced Remedies, Inc.

Encl.
HM/ch

c:\letters\letter.hm

RECEIVED
JUL 07 1995
GENERIC DRUGS

ADVANCED REMEDIES, INC.
72-6 VERONICA AVENUE
SOMERSET, NJ 08873
(908) 846-8066 • FAX (908) 846-7952

March 16, 1998

via Telecopy to: (301)443-3839

Roger L. Williams, M.D., Director
Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773

Re: ANDA 74-706
Cromolyn Sodium Ophthalmic Solution 4%
TELEPHONE AMENDMENT

Dear Dr. Williams:

This letter shall serve to confirm my telephone conversation of this date with Ms. Andrea High of your office. As I discussed with Ms. High, we are committing to perform additional should from and in the subject drug product.

Please do not hesitate to contact me if you require additional information.

Sincerely,

Hari Menon
President

HM/sta

cc: Ms. Andrea High

**ADVANCED REMEDIES, INC.**
72-6 VERONICA AVENUE
SOMERSET, NJ 08873
(908) 846-8066 • FAX (908) 846-7952

AMENDMENT
N/A C

September 25, 1996

via Airborne Express

RECEIVED
SEP 26 1996
GENERIC DRUGS

Dr. Roger L. William, Director
Office of Generic Drugs; CDER, FDA
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

Re: Cromolyn Sodium Ophthalmic Solution USP, 4%
ANDA # 74-706
MAJOR AMENDMENT

Dear Dr. William:

Enclosed please find our responses to the deficiencies outlined in your correspondence of March 6, 1996, regarding the above referenced application.

We are also acknowledging that our firm will be in CGMP compliance at the time of approval, and the USP analytical method will prevail over alternate methods in the event of a dispute.

Please note that the manufacturer of the drug substance has changed their manufacturing process. They are now using I am also submitting a copy of our response to the FDA district office for their records.

I trust our responses meet your requirements for obtaining the approval of this product. Thank you for your continued cooperation.

Sincerely,

Hari Menon,
President

HM/sta
Enclosures

cc: U.S. Food & Drug Administration (w/encls.)
Attn: Mr. Frank O'Sullivan

**ADVANCED REMEDIES, INC.**
72-6 VERONICA AVENUE
SOMERSET, NJ 08873
(908) 846-8066 • FAX (908) 846-7952

September 9, 1997

via Airborne Express

NDA ORIG AMENDMENT

Roger L. Williams, M.D., Director
Office of Generic Drugs, CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

Re: Cromolyn Sodium Ophthalmic Solution USP, 4%
ANDA 74-706
MAJOR AMENDMENT

Dear Dr. Williams:

Reference is made to your correspondence dated February 7, 1997, March 13, 1997 and also our telephone conversation with the agency representative dated June 23, 1997 regarding the above mentioned application.

Enclosed please find our responses to the deficiencies outlined in your communications stated above. This amendment is made as per your request dated June 23, 1997 and I trust our responses meet your requirements for obtaining the approval of this product.

Thank you for your continued cooperation.

Very truly yours,

Hari Menon
President

HM/sta
Enclosures

cc: U.S. Food & Drug Administration
Attn: Ms. Regina Brown (w/encls.)

RECEIVED
SEP 1[illegible] 1997
GENERIC DRUGS

**ADVANCED REMEDIES, INC.**
72-6 VERONICA AVENUE
SOMERSET. NJ 08873
(908) 846-8066 • FAX (908) 846-7952

September 5, 1995

Dr. Roger L. William, Director
Office of Generic Drugs
CDER, FDA
MPN II, HFD-600
5600 Fishers Lane
Rockville, MD 20857

Re: **Cromolyn Sodium Ophthalmic Ointment USP, 4%**
**ANDA # 74-706**

Dear Dr. William:

Reference is made to your communication dated August 22, 1995 regarding the above mentioned ANDA.

As an amendment, enclosed you will find the responses to the deficiencies that were made in your communication as follows:

1. Form 356h with an original signature.

2. Compliance certification with related to federal, state and local environmental laws and regulations.

3. Certification of non acquirement of debarred or convicted personnel with an original signature. We are again providing information regarding "affiliated persons" debarment or conviction certification. Please note that this information is already included in our original application under section X.3.

If you need any further information please feel free to contact me.

Sincerely yours,

Hari Menon
President
Advanced Remedies, Inc.

Encl.
HM/ch

cc: U.S. Food & Drug Administration
Attn: Mr. Frank O'Sullivan

RECEIVED
SEP 0 6 1995
GENERIC DRUGS

**ADVANCED REMEDIES, INC.**
72-6 VERONICA AVENUE
SOMERSET, NJ 08873
(908) 846-8066 • FAX (908) 846-7952

February 27, 1998

via Airborne Express

Roger L. Williams, M.D., Director
Office of Generic Drugs; CDER, FDA
Document Control Room
Metro Park North II
7500 Standish Place
Rockville, MD 20855-2773

ORIG AMENDMENT

Re: Cromolyn Sodium Ophthalmic Solution USP, 4%
ANDA 74-706
MINOR AMENDMENT

Dear Dr. Williams:

Reference is made to your correspondence dated February 11, 1998, regarding the above mentioned application.

Enclosed please find our responses to the deficiencies outlined in your communication stated above. I trust our responses meet your requirements for obtaining approval of this product.

Thank you for your continued cooperation.

Sincerely,

Hari Menon
President

HM/sta
Enclosures

cc: Food & Drug Administration
Attn: Ms. Regina Brown (w/encls.)

RECEIVED
MAR
GENERIC DRUGS