# CENTER FOR DRUG EVALUATION AND RESEARCH

*APPLICATION NUMBER:*

**84902**

## CHEMISTRY REVIEW(S)

| CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Statement Date: | NDA # 84-902 |
|---|---|---|

NAME AND ADDRESS OF APPLICANT:

Alcon Laboratories, Inc.
Fort Worth, TX 76101

ORIGINAL
AMENDMENT XXX
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

Bioavailability data

DATE(s) of SUBMISSION(s)

9-3-80; 6-25-81

| PHARMACOLOGICAL CATEGORY | NAME OF DRUG | HOW DISPENSED |
|---|---|---|
| antihistamine | Promethacon (promethazine HCl) | RX xxxx OTC _____ |
| DOSAGE FORM: suppository | POTENCY(IES): 50 mg. | RELATED IND/NDA/DMF |
| STERILIZATION: N.A. | SAMPLES: validated | |

LABELING: FPL satisfactory per Dr. Seife 10-1-81

BIOLOGIC AVAILABILITY

Satisfactory per Dr. Pelsor review 6-25-81

ESTABLISHMENT INSPECTION

Satisfactory per 7-17-81

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Previously reviewed by J. Taylor 2-19-76.

PACKAGING

Satisfactory

STABILITY:

Protocol: Nine months data at 35°C shows product is stable. Room temperature data submitted for 6-9 months then skips to 36 months. All 36 month data slightly less than 90% of label by USP method. method consistently higher % than USP assay.

Exp. Date: Propose two years.

REMARKS & CONCLUSION:

approval

REJoyce 10-1-81

| | | |
|---|---|---|
| FIRST 3 REVIEWS FOR NEW DRUG APPLICATION OR SUPPLEMENT | Federal Register Statement Date | NDA Number 8-902 |
| | | AE Number 27-736 |

Name and Address of Applicant (City and State)
**Alcon Laboratories, Inc.**
**Mfg: Kansas, MO**

Original
Amendment XX
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement
**Labeling, stability**

Date(s) of Submission(s)
**12-5,15,1976**

| Pharmacological Category | Name of Drug | |
|---|---|---|
| **antihistamine** | **Promethazine HCl** | |
| **Dosage Form(s)** | **Potency(ies)** | **How Dispensed** |
| **suppository** | ~~25 mg.~~ **50 mg.** | ~~Rx~~ X OTC |
| **Packaging/Sterilization** | **Samples** | **Related IND/NDA/DF** |
| **Foil pouch/EA** | **Received--not yet sent** | ✓ **8-901 25 mg.** **8-902 50 mg.** |

Labeling
**Satisfactory for container. (Mfgr) Insert may require revision if bio study so indicates**

Biologic Availability
**Required per current ruling--see memo of 12-5 meeting**

Establishment Inspection
**Satisfactory**

Components, Composition, Manufacturing and Controls
**Satisfactory as presumb--if bio indicates a particular chemical test would help insure bioavailability reproducibility additional tests will be required at that time.**

Remarks
**Request 7EA container**
**Bio required**



Conclusion Rev w/l 2-19-76

Reviewer

| CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Federal Register Statement Date | NDA Number 84-902 [redacted] AE Number 27-736 |
|---|---|---|

Name and Address of Applicant (City and State)

**Alcon Laboratories, Inc.**
**Ft. Worth, TX 76101**

Original ____
Amendment XX
Supplement ____
Resubmission ____
Correspondance ____
Report ____
Other ____

Purpose of Amendment/Supplement

**Stability data preliminary**

Date(s) of Submission(s)

**October 7, 1975**

| Pharmacological Category | Name of Drug | |
|---|---|---|
| **antihistamine** | **Promethazine Hydrochloride** | |
| Dosage Form(s) **Suppository** | Potency(ies) ~~25 mg.~~ **50 mg.** | How Dispensed ~~Rxxxx~~ X OTC |
| Packaging/Sterilization **Foil/PE** | Samples **requested** | Related IND/NDA/NF ✓ **84-901 25 mg.** **84-902 50 mg.** |

Labeling

**See previous review**

Biologic Availability

**Not required at ~~present~~present, no additional clinical data required (Meife)**

Establishment Inspection

**Satisfactory**

Components, Composition, Manufacturing and Controls

**See previous review**

Remarks

**Request information as before. Acknowledge stability commitment.**

Conclusion Rev w/f /S/ 10-20-75

| CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT | Federal Register Statement Date 6/18/71 | ANDA Number 84-902 AF Number 27-736 |
|---|---|---|

Name and Address of Applicant (City and State)

Alcon Laboratories, Inc.
Ft. Worth, TX 76101

Original xx
Amendment
Supplement
Resubmission
Correspondance
Report
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
September 9, 1975

| Pharmacological Category | Name of Drug | |
|---|---|---|
| antihistamine | Promethacon Supprettes<br>Promethazine Hydrochloride | |
| Dosage Form(s) | Potency (ies) | How Dispensed |
| suppository | 50 mg. | Rxxxx<br>X<br>OTC |
| Packaging/Sterilization | Samples | Related IND/NDA/MF |
| Foil/polyester/PE<br>next to drug heat seal | Requested gs<br>~~Not required~~ | 1<br>84-901 25 mg. |

Labeling
Satisfactory (JRCarr)

Biologic Availability
Deferred

Establishment Inspection
Requested

Components, Composition, Manufacturing and Controls
Satisfactory per application

Remarks

1. FPL of insert/carton. 2. Proposed immediate container labeling.
3. Composition of the coloring agent--

Conclusion Rec w/f

REVIEWER v |S| DATE 9-23-75