

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

84902

MEDICAL REVIEW

REVIEW OF LABELING

DATE COMPLETED: 2-16-79

ANDA #: 84-901
84-902

CO. NAME: Alcon Laboratories, Inc.
Ft. Worth, TX 76101

APPROVAL DATE: NONE

NAME OF DRUG: Promethazine Hydrochloride Suppositories, 25 mg., 50 mg..

DATE OF SUBMISSION:

REVIEW OF LABELING:

Package insert: Needs revision

CONCLUSION: Package insert must be revised in accord with current up-dated labeling guidelines.

RECOMMENDATIONS: The company is to be so notified and sent a copy of the labeling guidelines.

/S/
J.R. Carr, D.D.S.

CC:
DUP
JRC/wlh/2-16-79