CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

84902

APPROVAL LETTER

OCT 5 1981

NDA 84-902

Alcon Laboratories, Inc.
Attention: Roger O. Metzler
6201 South Freeway
P.O. Box 1959
Fort Worth, TX 76101

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Promethacon (promethazine hydrochloride) Suppositories, 50 mg.

We also acknowledge receipt of your communications dated June 25, 1981 and September 1, 1981 amending the application.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application, requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration 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 immediate advertising or promotional campaigns. Please submit both copies and a completed form FD-2253, together with a copy of the Final Printed Labeling, to the Division of Drug Advertising (HFD-170). A copy of Form FD-2253 is enclosed for your convenience.

We call your attention to regulation 21 CFR 310.300(b)(3) which requires that material for any subsequent advertising or promotional campaigns, at the time of their initial use, be submitted to our Division of Drug Advertising (HFD-170) with a completed form FD-2253.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

/S/ 10/5/81

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

Enclosures:
Conditions of Approval of a New Drug Application
Records & Reports Requirements
Form FD 2253

cc:
DAL-DO
dup
HFD-614
HFD-530
HFD-313
HFD-5
MSeife/JMeyer/REJoyce 10/2/81
r/d/ init. JMeyer/MSeife 10-2-81
f/t/wh/10-2-81 JMeyer 10/2/81
approved