DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20852

NDA 83-426

Danbury Pharmacal, Inc.
Attention: Mr. Ira Sacks
131 West Street
Danbury, CT 06810

SEP 19 1973

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 Promethazine Hydrochloride Tablets, 25 mg.

Reference is also made to your communication dated August 20, 1973, enclosing manufacturing information and labeling.

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 130.9 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

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

Sincerely yours,

Paul A. Bryan, M.D.
Acting Deputy Director for
Medical Affairs
Office of Scientific Evaluation
Bureau of Drugs

Enclosures:
Conditions of Approval of a New Drug Application
Records and Reports Requirement