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

NDA 80-356

JAN 17 1972

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

Gentlemen:

Reference is made to your abbreviated new drug application dated April 19, 1971, submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prednisone Tablets, 5 mg.

Reference is also made to your communication dated December 9, 1971, enclosing printed 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.

The periodic reporting requirements of Section 130.13(b)(4) of the new drug regulations are waived in regard to this application as published in the Federal Register of October 21, 1970.

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.

Our action in approving this application is based upon an understanding that when more precise tests become available to determine the biologic availability of this drug you will perform these tests.

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

Sincerely yours,

Paul A. Bryan, M.D.

Paul A. Bryan, M.D.
Director
Drug Efficacy Study Implementation
Project Office
Bureau of Drugs

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