

NOV 12 1976

NDA 85-162

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

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 Prednisone Tablets, 10 mg.

We acknowledge receipt of your communication dated June 18, 1976 enclosing final printed labeling and additional control information.

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.

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.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

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

Sincerely yours,

*for R. Barzilai*  
Marvin Seife, M.D.

Director  
Division of Generic Drug Monographs  
Office of Drug Monographs  
Bureau of Drugs

*11/14/76*

*R. Barzilai*  
*11/10/76*  
B-BOS-DO DUP HFD-614, HFD-616  
RBarzilai/JLMeyer/JMRoss  
R/Dinit.JMeyer/MSeife  
ft/cjb/11-10-76  
approved

Enclosures:

*11-10-76* *JMeyer 11/11/76*  
Conditions of Approval of a New Drug Application  
Records & Reports Requirements