

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

86683

APPROVAL LETTER

MAY 11 1979

NDA 86-683

Purepac Pharmaceutical Company
Attention: Ms. Sandi Feldman
200 Elmora Avenue
Elizabeth, NJ 07207

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 Acetaminophen 300 mg. and Codeine Phosphate 60 mg. Tablets.

Reference is also made to your communication dated April 16, 1979, enclosing the final printed labeling and stability 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.

cc: NWK-DO DUP HD-614
JRCarr/JMeyer/OChang
r/d/ init. Meyer/Seife 5-9-79
E/t/wlh/5-10-79
approval
5/11/79

Sincerely yours,

MS
Martin/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