CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

86954

APPROVAL LETTER

SEP 6

NDA 86-954

Lederle Laboratories
Attention: Andrew G. Anderson
North Middletown Road
Pearl River, NY 10965

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 Probenecid with Colchicine Tablets, 500 mg/0.5 mg.

Reference is also made to your communication dated August 17, 1979 amending the application.

The application provides for you to repackage the drug product received from Danbury Pharmaceuticals, Danbury, CT.

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.

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.

/S/ 9/6/79

[illegible], M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

NYK-DO DUP HFD-614
RBarzilai/JLMeyer/CMSmith
R/DinitJMeyer/MSeife
ft/cjl/9-5-79 approved
CM Smith 9-5-79
JMeyer 9/5/79
9/5/79

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