

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

86954

MEDICAL REVIEW

REVIEW OF ANDA

DATE COMPLETED: 4-24-79

ANDA #: 86-954

CO. NAME: Lederle Laboratories

NAME OF DRUG: Probenecid (500 mg.) with Colchicine (0.5 mg.) Tablets

DATE OF SUBMISSION: 3-19-79

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: EIAR - for review by assigned chemist.
Bio studies - deferred

2. Review of Labeling:

Container labels: Acceptable FPL for containers of 100 and 1000s

Package insert: Acceptable FPL

CONCLUSION:

1. Need chemists review.
2. Acceptable FPL

RECOMMENDATIONS: Notify firm.


R. Barzilai, M.D.

cc:dup
REB/wlf/5-2-79