

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

85552

MEDICAL REVIEW

REVIEW OF ANDA

DATE COMPLETED: 1-4-77

ANDA #: 85-552

CO. NAME: Chelsea Labs., Inc.

NAME OF DRUG: Trade: Proben-C

Generic: Probenecid 500 mg. with Colchicine 0.5 mg. Tablets

DATE OF SUBMISSION: 12-14-76

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: EIAR for review by assigned chemist.
Bio studies - deferred
2. Review of Labeling: Acceptable FPL of labels (containers of 100 and 1000's) and insert.

CONCLUSION: Acceptable FPL as above.

RECOMMENDATIONS: Notify firm after chemists review.

/S/
R. Barzilai, M.D.

cc:
Dup
REB/wlb/1-4-77