

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

83221

MEDICAL REVIEW

REVIEW OF ANDA

DATE COMPLETED: Dec. 4, 1972 ANDA # 83-221

F.R. DATE: 7-28-72

CO. NAME: Bolar Pharm. Co., Inc.
130 Lincoln Street
Copiague, New York 11726

NAME OF DRUG: Trade & Generic: Probenecid Tablets, 0.5 gm. with Colchicine
0.5 mg. (100 tablets)

DATE OF SUBMISSION: Sept. 12, 1972

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:

- a) Bioavailability requirement is presently deferred for this drug.
- b) Manufacturing information, ingredients, etc., will be reviewed by the chemist.

2. Review of Labeling:

Container label: Draft copies of the proposed labels are submitted; they are satisfactory.

Package insert: Draft copy of the submitted insert requires revision in the section on INDICATIONS, CONTRAINDICATIONS, WARNINGS, PRECAUTIONS And on DOSAGE AND ADMINISTRATION.

CONCLUSION: Revision of the package insert is necessary.

RECOMMENDATIONS: Request revision of the package insert. Forward a copy of our guidelines to the firm.

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J. Bacsanyi, M.D.

cc:
Dup
BD-69
JBacsanyi/wlb/12-8-72