

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

84279

MEDICAL REVIEW

3 72

REVIEW OF ANDA

DATE COMPLETED: 6-4-74

ANDA #: 84-279

CO. NAME : Danbury Pharmacal, Inc.
131 West Street
Danbury, CT 06810

NAME OF DRUG: Trade: Col-Probenecid
Generic: Probenecid 500 mg. and Colchicine 0.5 mg. Tabs.

DATE OF SUBMISSION: 4-10-74

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies:
 - a. Bioavailability requirement is presently deferred for this drug.
 - b. The submitted manufacturing information will be evaluated by the chemist.

2. Review of Labeling:

- a. Container labels: The submitted FPL is satisfactory
- b. Package insert: The submitted FPL is satisfactory

CONCLUSION: The submitted FPL is satisfactory

RECOMMENDATION: The firm is to be so notified.

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J. Vacsanyi, M.D.

cc:

Dup

HFD-107

JTBacsanyi, M.D./kim/6-5-74