

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

86130

MEDICAL REVIEW

REVIEW OF RESUBMISSION

DATE COMPLETED: 2-8-78

ANDA #: 86-130

APPROVAL DATE: NONE

CO. NAME: Premo Pharm. Labs., Inc.
S. Hackensack, NJ 07606

NAME OF DRUG: Probenecid 0.5 g. with Colchicine 0.5 mg. Tablets

DATE OF SUBMISSION: 1-26-78

TYPE OF SUBMISSION: Resubmission

CLINICAL EVALUATION:

1. Review of Studies: none submitted

2. Review of Labeling:

Container labels for containers of 100 and 1000 tablets - satisfactory.

Package insert: satisfactory

CONCLUSION: The labeling in this submission is acceptable.

RECOMMENDATIONS: The company is to be so notified.

JS
J.R. Carr, D.D.S.

cc:dup JRC/wlb/2-8-78

REVIEW OF ANDA

DATE COMPLETED: 11-28-77

ANDA #: 86-130

F.R. DATE: 7-28-72

CO. NAME & ADDRESS:
Premo Pharmaceutical Lab
South Hackensack, NJ 07606

NAME OF DRUG: Probenecid 0.5 g with Colchicine 0.5 mg Tablets

DATE OF SUBMISSION: 11-4-77

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of studies:

Bioavailability requirement is deferred for this drug

2. Review of labeling:

a. Container labels: draft copies for containers of 100 and 1000 tablets
satisfactory

b. Package insert: (copy)

Under dosage and administration, proof read, and revise the first
parpgraph in accord with labeling guidelines

CONCLUSION: 1. The draft copies of the container labels are satisfactory.
Send in FPL
2. The copy of the package insert needs correction as noted above
after correcting send in FPL

RECOMMENDATIONS: The company is to be so notified

JSI
J.R. Carr, D.D.S.

cc:
Dup
JRCarr/mlb/11-28-77