

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

86130

ADMINISTRATIVE DOCUMENTS

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NOA NUMBER

86-130

DATE APPROVAL LETTER ISSUED

TO:

Press Relations Staff (HFI-40)

FROM:

Bureau of Drugs

Bureau of Veterinary Medicine

ATTENTION

Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.

TYPE OF APPLICATION

ORIGINAL NDA

SUPPLEMENT

ABBREVIATED

SUPPLEMENT

CATEGORY

HUMAN

VETERINARY

GENERIC NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG

DOSAGE **Probenecid with Colchicine**

HOW DISPENSED

RX

OTC

tablets

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

Probenecid 500 mg.
Colchicine 0.5 mg.

NAME OF APPLICANT (Include City and State)

Premo Pharmaceutical Labs., Inc. - S. Hackensack, NJ 07606

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY

anti-gout

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME

CChang

DATE

2-27-86

FORM APPROVED BY

NAME

JLMeyer

DATE