CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

86954

CHEMISTRY REVIEW(S)

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Desi # XX 12-383	NDA 86-954
NAME AND ADDRESS OF APPLICANT: Lederle Laboratories (Repackager) Pearl River, NY 10954		ORIGINAL AMENDMENT SUPPLEMENT RESUBMISSION CORRESPONDENCE REPORT OTHER
PURPOSE OF AMENDMENT/SUPPLEMENT		DATE(s) of SUBMISSION(s) 3/19/79 8/17/79
PHARMACOLOGICAL CATEGORY Uricosuric	NAME OF DRUG Probenecid with Colchicine	HOW DISPENSED RX X OTC ____
DOSAGE FORM Tablets	POTENCY(IES) Probenecid 500 mg Colchicine 0.5 mg	RELATED IND/NDA/DMF DMF
STERILIZATION	SAMPLES	NDA 84-279 (Danbury Pharm.)

LABELING

Satisfactory per REbarzilai

BIOLOGIC AVAILABILITY

Not required, applicant is repackager Product mfg by Danbury Pharm

ESTABLISHMENT INSPECTION

Applicant in compliance, memo dated 7/20/79

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Controls are satisfactory

PACKAGING

Satisfactory

STABILITY:

Protocol: Submitted

Exp. Date: 2 years

REMARKS & CONCLUSION:

approval
CMSmith