CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

86681

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA # 86-681

NAME AND ADDRESS OF APPLICANT:

Purepac Pharm. Co.
Elizabeth, NJ 07207

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION xxx
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

labeling and control info.

DATE(s) of SUBMISSION(s)

as per letter

PHARMACOLOGICAL CATEGORY	NAME OF DRUG
analgesic	apap + codeine PO4
DOSAGE FORM	POTENCY(IES)
tablets	300 + 30 mgs.
STERILIZATION	SAMPLES

HOW DISPENSED

RXxxxx OTC _____

RELATED IND/NDA/DMF

86-681 300 + 30

LABELING

satisfactory per MO JRCarr

BIOLOGIC AVAILABILITY

na

ESTABLISHMENT INSPECTION

satisfactory 11-21-78

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

~~see issued letter~~ satisfactory

PACKAGING

satisfactory.

STABILITY:

Protocol: satisfactory

Exp. Date: 2 years with accelerated data

REMARKS & CONCLUSION:

APPROVAL CCHANG a. dly 6-10-79

CHEMIST's REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA NUMBER: 86-681

E AND ADDRESS OF APPLICANT

Purepac Pharm. Co.
Elizabeth, NJ 07207

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION XXXXC
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

labeling and control informatio n

DATE(s) of SUBMISSION(s)
as per letter

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
Analgesic	Apap + PO_4 Codeine	RXXXXXXX OTC
DOSAGE FORM(S)	**POTENCY(IES)**	**RELATED IND/NDA/DMF**
Tablets	300 + 30 mgs.	86-681 300+30 mg.
STERILIZATION	**SAMPLES**	

LABELING

satisfactory per MO J.R. Carr

BIOLOGIC AVAILABILITY

NA

ESTABLISHMENT INSPECTION

Requested

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

See issued letter

PACKAGING

Requested

STABILITY

Protocol: See issued letter

Exp. Date: requested

REMARKS AND CONCLUSION: rev w/f CChang C. Cley 2-16-79

CHEMIST's REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA NUMBER: 86-681

NAME AND ADDRESS OF APPLICANT
Purepac Phar. Co.
Elizabeth, NJ 07207

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

DATE(s) of SUBMISSION(s)
as per letter

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
analgesic	APAP + Codeine PO_4	RX XXXX OTC
DOSAGE FORM(S)	**POTENCY(IES)**	**RELATED IND/NDA/DMF**
Tablets	300 +30 mgs.	86-681 300 + 30 mg.
STERILIZATION	**SAMPLES**	

LABELING
Unsatisfactory per MO JR. Carr

BIOLOGIC AVAILABILITY
NA

ESTABLISHMENT INSPECTION
Requested

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS
See issued letter.

PACKAGING
Requested

STABILITY
Protocol: See issued letter
Exp. Date: Requested

REMARKS AND RECOMMENDATIONS:
Rev w/f C. Chang C. Chang 11-3-78