CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

86683

CHEMISTRY REVIEW(S)

CHEMIST'S REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA # 86-683

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 + 60 mgs.
STERILIZATION	SAMPLES

HOW DISPENSED

RX xxxx OTC _____

RELATED IND/NDA/DMF

✓ 86-683 300 + 60
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 w. accelerated data

REMARKS & CONCLUSION:

APPROVAL CCHANG /S/ 5-10-79

CHEMIST's REVIEW FOR ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA NUMBER: 86-683

IE AND ADDRESS OF APPLICANT

Purepac Pharm Company
Elizabeth, NJ 07207

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION XXX
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

Labeling & Control information

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

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
Analgesic	APAP + PO_4 Codeine	RX XXXX OTC
DOSAGE FORM(S)	**POTENCY(IES)**	**RELATED IND/NDA/DMF**
Tablets	300 + 60 mgs.	86-683 300 + 60 mg. 86-681 300 +30 mg.
STERILIZATION	**SAMPLES**	

LABELING

satisfactory per MOr 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 C. Chang /S/ 2-22-79

CHEMIST'S REVIEW FOR
ABBREVIATED NEW DRUG APPLICATION
OR SUPPLEMENT

Statement Date:

NDA NUMBER:
86-683

NAME AND ADDRESS OF APPLICANT

Purepac Pharm. Company
Elizabeht, NJ 07207

ORIGINAL XXXX
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 XXX OTC
DOSAGE FORM(S)	**POTENCY(IES)**	**RELATED IND/NDA/DMF**
Tablets	300 + 60 mgs.	86-683 300 +60 mg. 86-681 300 +30 mg.
STERILIZATION	**SAMPLES**	

LABELING

Unsatisfactory per MO JRCarr

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

ISI 10-25-85