

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**86681**

**MEDICAL REVIEW**



REVIEW OF ANDA

DATE COMPLETED: 10-10-78

ANDA #: 86-681

CO. NAME: Purepac Pharm. Co.  
Elizabeth, NJ 07207

F.R. DATE: 2-2-73

NAME OF DRUG: Acetaminophen 300 mg. with Codeine Phosphate 30 mg. Tablets

DATE OF SUBMISSION: 9-18-78

TYPE OF SUBMISSION: ANDA

CLINICAL EVALUATION:

1. Review of Studies: Bioavailability requirement is deferred for this drug.

2. Review of Labeling:

Container labels: draft copies for containers of 100 and 1000 tablets -- satisfactory

Package insert: draft copy - needs revision

CONCLUSION:

1. The draft copies of the container labels are satisfactory
2. The draft copy of the package insert needs revision in accord with labeling guidelines.

RECOMMENDATIONS: The company is to be so notified and sent a copy of the labeling guidelines.

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J.R. Carr, D.D.S.

cc:dup  
JRC/wlh/10-11-78