

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**86681**

**ADMINISTRATIVE DOCUMENTS**

|                                                                                                                                                                                                                                                                    |  |                                                                                                                                        |
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| <b>NOTICE OF APPROVAL</b><br><b>NEW DRUG APPLICATION OR SUPPLEMENT</b>                                                                                                                                                                                             |  | NDA NUMBER<br><hr/>                                                                                                                    |
| TO: <b>Press Relations Staff (HFI-40)</b>                                                                                                                                                                                                                          |  | FROM: <input checked="" type="checkbox"/> Bureau of Drugs <b>MAY 11 1979</b><br><input type="checkbox"/> Bureau of Veterinary Medicine |
| ATTENTION<br>Forward original of this form for publication only after approval letter has been issued and the date of approval has been entered above.                                                                                                             |  |                                                                                                                                        |
| TYPE OF APPLICATION: <b>ORIGINAL ABBREVIATED</b><br><input type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO NDA <input checked="" type="checkbox"/> ORIGINAL NDA <input type="checkbox"/> SUPPLEMENT TO ANDA                                  |  | CATEGORY<br><input checked="" type="checkbox"/> HUMAN <input type="checkbox"/> VETERINARY                                              |
| TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG<br><b>Acetaminophen and Codeine Phosphate</b>                                                                                                                        |  |                                                                                                                                        |
| DOSAGE FORM<br><b>Tablets</b>                                                                                                                                                                                                                                      |  | HOW DISPENSED<br><input checked="" type="checkbox"/> <b>RECIPE</b> <input type="checkbox"/> OTC                                        |
| ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)<br><br><div style="margin-left: 40px;"> <b>Acetaminophen 300 mg.</b><br/> <b>Codeine Phosphate 30 mg.</b> </div> |  |                                                                                                                                        |
| NAME OF APPLICANT (Include City and State)<br><b>Purpax Pharmaceutical Co.</b><br><b>Elizabeth, NJ 07207</b>                                                                                                                                                       |  |                                                                                                                                        |
| PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY<br><br><div style="margin-left: 40px;"> <b>analgesic</b> </div>                                                                                                                                                   |  |                                                                                                                                        |
| COMPLETE FOR VETERINARY ONLY                                                                                                                                                                                                                                       |  |                                                                                                                                        |
| ANIMAL SPECIES FOR WHICH APPROVED                                                                                                                                                                                                                                  |  |                                                                                                                                        |
| COMPLETE FOR SUPPLEMENT ONLY                                                                                                                                                                                                                                       |  |                                                                                                                                        |
| CHANGE APPROVED TO PROVIDE FOR                                                                                                                                                                                                                                     |  |                                                                                                                                        |
| FORM PREPARED BY<br>NAME <b>Chang</b>                                                                                                                                                                                                                              |  | DATE<br><b>5-10-79</b>                                                                                                                 |
| FORM APPROVED BY<br>NAME <b>Mayer</b>                                                                                                                                                                                                                              |  | DATE                                                                                                                                   |