

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

86683

ADMINISTRATIVE DOCUMENTS

**NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT**

DATE APPROVAL LETTER ISSUED

TO: **Press Relations Staff (HFI-40)**

FROM: **MAY 11 1979**
 Bureau of Drugs
 Bureau of Veterinary Medicine

ATTENTION
 Forward original of this form for products for which approval letter has been issued and the date of approval has been **ORIGINAL ABBREVIATED**

TYPE OF APPLICATION: ORIGINAL NDA SUPPLEMENT TO NDA ABBREVIATED ORIGINAL NDA SUPPLEMENT TO ANDA

CATEGORY: HUMAN VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG:
Acetaminophen and Codeine Phosphate

DOSEAGE FORM: **Tablets**

HOW DISPENSED: **As Shown** 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.)

**Acetaminophen 300 mg.
Codeine Phosphate 60 mg.**

NAME OF APPLICANT (include City and State):
**Paropec Pharmaceutical Co.
Elizabeth, NJ 07207**

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY:
analgesic

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY: **CS/ang** DATE: **5-10-79**

FORM APPROVED BY: **[Signature]** DATE:

business hours, Monday through Friday. This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 505, 52 Stat. 1052-53, as amended; 21 U.S.C. 355), and the Administrative Procedure Act (5 U.S.C. 554), and under authority delegated to the Commissioner (21 CFR 2.120).

Dated: January 26, 1973.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.73-2016 Filed 2-1-73;8:45 am]

[DESI 7289]

**CODEINE WITH ACETAMINOPHEN,
ASPIRIN, AND CAFFEINE FOR ORAL USE**
Drugs for Human Use; Drug Efficacy Study
Implementation

The Food and Drug Administration has evaluated a report received from the National Academy of Sciences—National Research Council, Drug Efficacy Study Group, on trisecic with codeine tablets (NDA 7-289) containing codeine, acetaminophen, aspirin, and caffeine; E. R. Squibb & Sons, Division Olin Mathieson Chemical Corp., 745 Fifth Avenue, New York, N.Y. 10022.

Such drugs are regarded as new drugs (21 U.S.C. 321(p)). Supplemental new drug applications are required to revise the labeling in and to update previously approved applications providing for such drugs. A new drug application is required from any person marketing such drug without approval.

A. *Effectiveness classification.* 1. The Food and Drug Administration has considered the Academy's report, as well as other available evidence, and concludes that combination drugs containing codeine with acetaminophen, aspirin, and caffeine are effective for the relief of mild to moderate pain.

B. *Conditions for approval and marketing.* The Food and Drug Administration is prepared to approve abbreviated new drug applications and abbreviated supplements to previously approved new drug applications under conditions described herein.

1. *Form of drug.* Preparations containing codeine, acetaminophen, aspirin, and caffeine are in tablet form suitable for oral administration.

2. *Labeling conditions.* a. The label bears the statement, "Caution: Federal law prohibits dispensing without prescription."

b. The drug is labeled to comply with all requirements of the Act and regulations, and the labeling bears adequate information for safe and effective use of the drug(s). The indication for use is: For the relief of mild to moderate pain.

3. *Marketing status.* Marketing of such drugs may be continued under the conditions described in the notice entitled Conditions for Marketing New Drugs Evaluated in Drug Efficacy Study, published in the FEDERAL REGISTER July 14, 1970 (35 FR 11273), as follows:

a. For holders of "deemed approved" new drug applications (i.e., an application which became effective on the basis of safety prior to October 10, 1963), the submission of a supplement for revised labeling and an abbreviated supplement for updating information as described in paragraph (a)(1)(i) and (iii) of the notice of July 14, 1970.

b. For any person who does not hold an approved or effective new drug application, the submission of an abbreviated new drug application as described in paragraph (a)(3)(i) of that notice.

c. For any distributor of the drug, the use of labeling in accord with this announcement for any such drug shipped within the jurisdiction of the Act as described in paragraph (b) of that notice.

A copy of the Academy's report has been furnished to the firm referred to above. Communications forwarded in response to this announcement should be identified with the reference number DESI 7289, directed to the attention of the appropriate office listed below, and addressed to the Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852.

Supplements (Identify with NDA number):
Office of Scientific Evaluation (BD-100),
Bureau of Drugs.

Requests for the Academy's report: Drug
Efficacy Study Information Control (BD-
66), Bureau of Drugs.

All other communications regarding this announcement: Drug Efficacy Study Implementation Project Office (BD-60), Bureau of Drugs.

All identical, related, or similar products, not the subject of an approved new drug application, are covered by the new drug application reviewed and are subject to this notice. See 21 CFR 130.40 (37 FR 23185, October 31, 1972). Any person who wishes to determine whether a specific product is covered by this notice should write to the Food and Drug Administration, Bureau of Drugs, Office of Compliance (BD-300), 5600 Fishers Lane, Rockville, MD 20852.

This notice is issued pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (secs. 502, 505, 52 Stat. 1050-53, as amended; 21 U.S.C. 352, 355) and the Administrative Procedure Act (5 U.S.C. 554) and under the authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120).

Dated: January 26, 1973.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.73-2017 Filed 2-1-73;8:45 am]

[Docket No. FDC-D-494; NADA No. 6-737V
and NADA No. 7-495V]

**HILLTOP LABORATORIES, INC. AND
BEEBE LABORATORIES, INC.**

Certain Drug Products Containing Sulfaquinolaxaline; Notice of Withdrawal of Approval of New Animal Drug Applications

In the FEDERAL REGISTER of November 30, 1972 (37 FR 25429), the Commissioner of Food and Drugs published a notice

proposing to withdraw approval of new animal drug application (NADA) No. 6-737V for Sulfaquin-O-Mor; marketed by Hilltop Laboratories, Inc., 2035 East Larpenteur Avenue, St. Paul, MN 55109 and NADA No. 7-495V for B-B-Q Liquid; marketed by Beebe Laboratories, Inc., 2035 East Larpenteur Avenue, St. Paul, MN 55109.

Neither the above named firms nor any other interested persons have filed a written appearance in response to the above cited notice. This is construed as an election by said persons not to avail themselves of the opportunity for a hearing.

Therefore, based on the grounds set forth in said notice of opportunity for a hearing, the Commissioner concludes that approval of said new animal drug applications should be withdrawn. Therefore, pursuant to provisions of the Federal Food, Drug, and Cosmetic Act (sec. 512, 52 Stat. 343-351; 21 U.S.C. 360b) and under authority delegated to the Commissioner (21 CFR 2.120), approval of NADA No. 6-737V and NADA No. 7-495V, including all amendments and supplements thereto, is hereby withdrawn effective on February 2, 1973.

Dated: January 26, 1973.

SAM D. FINE,
Associate Commissioner
for Compliance.

[FR Doc.73-2019 Filed 2-1-73;8:45 am]

[DESI 11160; Docket No. FDC-D-522;
NDA 11-160]

**PURDUE FREDERICK CO.;
THOREXIN COUGH MEDICINE**

Opportunity for Hearing on Proposal To Withdraw Approval of New Drug Application; Drug for Human Use; Drug Efficacy Study Implementation

Notice is hereby given to the Purdue Frederick Co., 99-101 Saw Mill River Road, Yonkers, N.Y. 80100, holder of NDA 11-160, Thorexin Cough Medicine, a liquid containing dextromethorphan hydrobromide, potassium gualacoi sulfonate, ammonium chloride, and antimony potassium tartrate, and to any interested person who may be adversely affected, that the Commissioner of Food and Drugs proposes to issue an order under section 505(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(e)) withdrawing approval of the above new drug application and all amendments and supplements thereto. It is proposed to withdraw approval of this new drug application on the grounds that new evidence, not contained in the new drug application or not available to the Commissioner until after the application was approved, evaluated together with the evidence available to him when the application was approved, reveals that Thorexin Cough Medicine is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.

The National Academy of Sciences—National Research Council, Drug Efficacy Study Group evaluated this drug

PUREPAC PHARMACEUTICAL CO.
DIVISION DRUGS, INC.
ELIZABETH, NEW JERSEY 07207

ABBREVIATED NEW DRUG APPLICATION FOR:
ACETAMINOPHEN 300 MG. WITH CODEINE PHOSPHATE
60 MG. TABLETS, U.S.P.